THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at The Westin Cincinnati, 21 East Fifth Street, Cincinnati, Ohio, on March 7, 2003.

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C O N T E N T S

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Mr. Mark Griffon, Workgroup Chair

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P R O C E E D I N G S

8:30 a.m.

REGISTRATION AND WELCOME

DR. ZIEMER: Good morning, everyone. I'm going to call the meeting to order. This is the twelfth meeting of the Advisory Board for Radiation and Worker Health. My name is Paul Ziemer, Chairman of the Board. The Board members are before me here at the table. We don't normally introduce them individually. They do have placards in front of them to help them remember who they are and to help you identify them, as well.

We remind all of you, Board members, visitors, Federal staff members, we would like to ask you to be sure to register your attendance here today. The registration book is just outside the door in the corridor, so if you've not already done that, please register your attendance with us here today.

Also members of the public who are interested in making comment during the public comment period, we ask that you sign up on the book that's so designated so that we have some idea of the numbers of individuals that wish to make public comment.

I would like to point out to you that it is my intent to alter the agenda somewhat with respect to

the public comment period. Incidentally, if you don't have an agenda, there are copies of the agenda, as well as other relevant materials, on the table -- is that the table in the corridor, as well? Yes. Or at the back of the room. Please pick up an agenda if you don't have one.

We show on the agenda the public comment period at the end of the meeting, but it occurred to me that it would be beneficial to the Board to receive public comments on the issue that's before us today before we ended our deliberations, so it's my intent to move the public comment period up to mid-day at the 1:30 hour, which is when we reconvene after lunch. So unless there are objections from either the Board or members of the public who wanted to comment, I will declare that that will be when we have our public comment period.

Let the record show that all of the Board members are present with the exception of Leon Owens, and Leon -- sorry, could not be here in person, but he's on the line. Leon, can you hear us?

MR. OWENS: Yes, sir, I can, Dr. Ziemer. Thank you.

DR. ZIEMER: Great, we can hear you very well,

as well. Thank you.

One important piece of information is that the restroom code -- you have to have a code to get in the restroom -- the restroom code is posted on the wall in the back by that house phone, so you can check the code and then use the facilities, which are down the hall going out the door to the right.

The focus of this meeting will be on the notice of proposed rulemaking dealing with the Special Exposure Cohort. That will be the primary focus. We have at least one other item that will come before us as we move along, but that will be our primary focus today as we proceed.

Now I'd like to turn the mike over to Larry Elliott for a few preliminary comments.

MR. ELLIOTT: While Dr. Ziemer's moving back to his chair at the table, I'd like to welcome you all to Cincinnati. It's nice to see you again. It seems like we're meeting on a monthly basis. This meeting will curtail that and we can jump to May. We'll have two months perhaps between meetings, at least for this -- the next one.

I appreciate you coming to town today for this one-day meeting to discuss the notice of proposed rulemaking on the petitioning process for adding

classes to the Special Exposure Cohort. This has been a long time in coming, I know. We are pleased that it's finally here. We look forward to your comments. We, as you know, produced a proposed rule last summer and this rule that you have before you today -- which is being published today by the *Federal Register,* will be open for public comment for 30 days hence -- is an outgrowth of the comments that we received on the proposed rule last summer. Because of the public comments that we received on that rule last summer and the changes that we made in addressing those comments, we are bound to come out with a notice of proposed rulemaking rather than finalize that rule from last summer. Had we done so, had we finalized the rule last summer, we felt it would have been unfair. This is totally a new look to this rule. So that's the explanation on why you have a notice of proposed rulemaking before you.

We're here today, Ted -- Ted Katz is here today to give you a presentation on this new rule. He will talk about how it is changed from the previous rule. We will provide clarification for you. We are not here to provide interpretation of intent in the rule.

Okay. I think, unless there's questions for

me, we have Ted up at the podium and I'll turn it back over to Dr. Ziemer in case he has any further opening remarks.

DR. ZIEMER: Thank you, Larry, and certainly we're happy that the rule is in our hands in time for the meeting. It would have been very difficult to have this meeting on rulemaking without the rule, or the proposed rule.

Let me ask a question. Are copies of the draft available for the public on the table at this point or is it dependent on its actual appearance in the *Federal Register* today?

MR. ELLIOTT: No, there are copies of the proposed rule on the table in the back.

DR. ZIEMER: Okay.

MR. ELLIOTT: It is in a format that is different than what the *Federal Register* format will be. Once it's published today, we will have on our web site a *Federal Register* formatted copy, so we'll put that up. It's probably going up this morning, as we speak. And then upon request, anybody that wants a *Federal Register* formatted copy, we will provide that hard copy to anyone who lets us know they'd like such.

DR. ZIEMER: Thank you. Ted, please proceed.

SPECIAL EXPOSURE COHORT - NOTICE OF PROPOSED RULE MAKING

MR. KATZ: Thank you, Dr. Ziemer. Can you hear me? Is this -- is this working?

DR. ZIEMER: Should be, yes.

MR. KATZ: Okay. I'm going to run through the major elements of the rule and give you the context for them, too -- meaning the sort of public comments we received, what the Board has said about these, et cetera. And then later today, when you get to the point where you're going -- if you're going to do this the way you've done the other rules in this previously, if you're going to go section by section in reviewing the rule, I would be happy to, if you want me to, section by section explain what changed and why. I'm not going to cover every little change in the presentation I give now, but I can hit actually every substantive change when we do that section by section so you're sure that you recognize everything that has been altered in this rule and why.

So let me begin just with a reminder of -- sorry about that.

Just to begin, a reminder that the two statutory criteria that we're to abide by in considering additions to the class here. One is

that it's not feasible to estimate with sufficient accuracy the radiation doses that the class received. And secondly, that there's a reasonable likelihood that such radiation dose may have endangered the health of the members of the class. So that is binding for us in what we propose in this rule.

Now in the first NPRM we said in the preamble that evaluating feasibility is not amenable to discrete litmus-type tests. That's still true. That's still true. You will not see in this rule a formula for deciding whether a class is to be added or not, and that it requires instead situation-specific determinations which would be reviewed by the petitioners, HHS and the Board. Again you'll see this is true.

And we also said that whenever we can estimate -- speaking of feasibility -- doses, our methods will provide that such estimates will be sufficiently accurate to support the fair adjudication of claims.

And as you recall, what that means -- when you think about how we do dose reconstructions, it means if we don't have sufficient personnel monitoring data and are pushed back to more limited data, as

far back even to just information on the source term and the processes involved, as we get pushed back from specific to more general data, the benefit of the doubt balloons in the favor of the claimant, which is why we're in a position to be able to say that we're not going to underestimate individual's doses as that information becomes more general.

Now the Board gave us advice about feasibility. It asked us to clarify in the preamble the criteria for determining that it was not possible to complete a dose reconstruction with sufficient accuracy. What was in the preamble, you may recall, was basically just a statement in effect that if there isn't sufficient -- if there isn't sufficient information to do a dose reconstruction, then we cannot estimate with sufficient accuracy. We've done better in this rule to clarify what that means.

And the Board also suggested we develop operational guidelines outlining criteria, including time limits, to address this issue of feasibility.

I'm just going to give you a sample, without comment, of the public comments suggesting when doses cannot be estimated. And these are -- they range really enormously in terms of understanding and perspective here from records are incomplete,

only coworker data available -- when only coworker data are available; in other words, you can't estimate doses -- when the identify of the source terms or solubility of energy is uncertain, when records are falsified, when workers were employed in multiple locations, when NIOSH cannot establish an upper bound on the dose, when dose reconstructions exceed a time limit. It's a pretty good representation of the comments we received.

Now here's the proposal that we have now, how this has changed. We say -- and this is consistent with one of the comments we received I just reviewed. It's feasible if we can -- if we have access to sufficient information to estimate the maximum radiation dose that could have been incurred in plausible circumstances by any member of the class. If we can put an upper bound on the dose to the class, then we can do the dose reconstructions. And again, sort of harking back to what I said before, as all we're doing is putting an upper bound on the dose, as we get to that point where we're so limited, there's an enormous amount of benefit of the doubt that's going to the claimants in that circumstance.

We also -- there's another provision in here

which is new, which is in some circumstances feasibility could be cancer site specific and hence cancer-specific.

Let me explain what's intended there. As you know, dose reconstructions are tissue-specific. We don't estimate doses generally. We estimate doses to the tissue related to the cancer that has been incurred. And hence, in fact in certain circumstances, it's possible that feasibility will hinge on which cancer site we're talking about. And let me just give you two examples to get this started.

An example of radon gas. If we can estimate all the radiation doses for an individual except for their exposure to radon, radon daughters, then the tissue -- the organ that is exposed to radiation is the lung. And for practical purposes, other tissues, other organs are not exposed. And we can do a -- in effect, cap the dose for those individuals with cancers other than lung cancer. We can't do it for lung cancer. And in that case, you would establish a class that included anyone who has or incurs in the future lung cancer and was exposed -- was at the site, et cetera. But it would be lung cancer-specific or lung tissue-specific, in effect.

And for all other individuals, you could take all their other doses, including this exposure to radon gas, radon, and calculate a dose for them, do a dose reconstruction for them.

Let me give you a second example. Instead of an internal emitter, let's talk about external exposure -- external dose where you have partial body radiation exposure. Say, for example, an individual -- individuals, workers, were exposed through a glove box. Or another circumstance where there's shielding and only a part of their body is being exposed. With the glove box, their skin would be exposed -- you know, their bones in their hand would be exposed, and that could relate to possibly three cancers: skin cancer, bone cancer and leukemia, blood-forming tissues in the red bone marrow in the hand. I mean those three cancers are possibly associated.

But for individuals who incur lung cancer, for example, you can do their dose reconstruction because the exposure that we're concerned about here that we can't estimate, in the glove box is not an exposure to their lungs. And the same would go for other organ site -- tissue sites.

Do you want me to pause on this or do you want

me to run through -- I mean you have my presentation. Do you want me to take questions as I go or --

DR. ZIEMER: Perhaps if questions pop up as you proceed, let's just go ahead and indicate.

MR. KATZ: So --

DR. ZIEMER: Otherwise --

MR. KATZ: So I'll carry through, and then of course we can visit all of this and will.

Okay. Now also the Board wanted us to give as much guidance as possible to the public about feasibility. And you know, in the hierarchy of information that we outlined in 42 CFR is in effect some of that guidance. It explains that, you know, if we don't have personnel monitoring data, we go to the next step and so on if we don't have good personnel monitoring data.

We also stated -- made a couple of statements in the rule that we thought would be helpful. This first, in general, you must be able to specify the types and quantities of radioisotopes to which the workers were potentially exposed. Or must know the design and performance information of radiation-generating equipment, such as particle accelerators. If we don't have such basic information, we may not

-- we're very likely not able to do a dose reconstruction, even doing that maximum dose that we just talked about.

And we also make a statement to the contrary, that in general -- you know, data from personal -- personal dosimetry and area monitoring are not essential. We thought it was important that the public understand that there is this hierarchy in effect and that while we prefer good personnel monitoring data, we can do dose reconstructions and they're fair to claimants based on more basic information.

In addition, we also committed in the preamble that we would publicize summaries of circumstances in which doses cannot be estimated as these arise from the dose reconstruction program. I mean so these will be illustrative cases, again, to help the entire public understand where our limits are, what sort of circumstances result in our being unable to estimate doses.

And we are of course committed to working with this Board to do whatever we can to expand guidance for the public on this topic.

Time limits. That's the other thing the Board mentioned. It was mentioned in public comments, as

well. And we'll consider establishing a time limit -- or guidelines for completing dose reconstructions once the dose reconstruction program reaches its full operating capacity. By time guidelines, I just mean to say -- I mean you may not want something so rigid as a time limit in certain circumstances. You may not want that if, for example, you could produce the dose reconstruction close to the time limit.

So moving to the next major element of this rule is how we deal with health endangerment. In the first proposal we proposed that we judge whether doses for a class could have exceeded a class-specific threshold to be derived from the cancer risk models from NIOSH-IREP.

And we also proposed that we would define a duration of employment requirement and would use the statutory criterion of 250 days as a default when we lacked a basis to diverge from it. That statutory criterion, that 250 days, relates to workers at the gaseous diffusion plants. That's the duration requirement that they have.

So that was in the first rule, both of these. The Board advised us -- they were concerned that the method of involving subjective judgment and cancer risk models could produce arbitrary and unfair

decisions. And you recommended, in general fashion, to consider other suitable criteria, which we have.

Some of the public comments suggesting how to determine health endangerment -- again, my intent is for you to just have an understanding of how the public viewed this subject. Use a qualitative approach, do not use NIOSH-IREP or any quantitative approach, provide more detail on how NIOSH-IREP were to be used -- if it were to be used; I think that was sort of a reluctant comment, if we were going to go down that path -- use physician opinion. I mean this comment was in effect to say treat it like you do an individual Workers Compensation case and have a physician make a determination. Use epidemiologic comparisons or use badge and 250-day criteria specified by Congress for the gaseous diffusion employees.

Now I mean there are certain implications of the dose reconstruction methods themselves that have a bearing on this and allowed us to change course here on this. When we can estimate at least a maximum dose for a class, we'd conduct dose reconstructions. When we can't estimate that maximum dose, then there's absolutely no practical benefit to quantifying this dose benchmark for

health endangerment because in any case the doses could actually have been above the benchmark, so there's no value to establishing a benchmark when we're talking about situations in which we can't put a cap on the doses. Because then, by definition, the doses could have been above the benchmark. That would have operated -- if we had retained that NIOSH-IREP provision in there, it would in effect have been sort of a moot provision, in reality, as we went through these petitions.

So what's our proposal for health endangerment. Well, we did eliminate the use of cancer risk models. There's no NIOSH-IREP in here. We limited determination to an employee duration requirement for exposed employees. We're not using the badge criterion here. It doesn't make sense here because we're being far more specific and can be far more specific about which employees we're talking about. We're retaining the 250-day requirement as a default. Again, that was in the first rule, as well, and we've kept it here. And we've allowed HHS -- us -- to specify presence as sufficient employment duration for discrete incidents in which doses were likely to have been exceptionally high.

We had a variety of public comments on petition

requirements. We had a request to expand the scope of eligible petitioners to non-union organizations such as LAPOWs. This is a informal organization of workers at Los Alamos -- from Los Alamos. Requests to eliminate the petition form, to eliminate the requirement that petitioners obtain verification of record deficiencies from DOE/AWEs. That was a provision in the first NPRM which would have been impractical for a number of circumstances, number of situations, particularly with the AWE employees. And we had a request to make independent health physics expertise available to potential petitioners, and this related to their concern that petitioners wouldn't have enough knowledge to meet the requirements for petitioning.

This is what we've proposed in response. We've expanded the scope of eligible petitioners. Now LAPOWs, any representative that's authorized in writing by the workers or survivors could serve as a petitioner. So I think that it is pretty wide open now in terms of who can petition. We made the use of petition forms voluntary, although I'll say I think the petition forms will be of assistance to petitioners and they'll probably see that they'll benefit by using them. We eliminated the

verification requirements. We eliminated the requirement to address health endangerment in the petition justification since, as you can see from how I've described how we're dealing with health endangerment, that's not going to have any value so we're not burdening petitioners with speaking to it. And we've simplified the petition justification concerning feasibility to set specific discrete options, in part responding to this concern that you need to be a health physicist to petition.

These are the specifics that we -- specific options that we address and a petition must support one of these options, or it could support more, but that exposures and doses were not monitored. And to be clear here, we're not saying that all doses to a class were not monitored. We're saying that there are doses to a class that were not monitored, so it's just -- if there's a subset of doses that were not monitored, that would cover this. If records were lost, falsified or destroyed. We also included if there's an expert report on record limitations at the facility and the necessity for dose reconstructions, if petitioner group wishes to hire a health physicist to make such a report, that could satisfy our need. Or any published -- and this is a

-- this came out of a Board recommendation, but any published scientific report on record limitations relevant to the petition could also serve. And these are specified in more detail in the rule. You can...

And another big issue, timeliness. Public comments -- the public was very concerned about expediting consideration of petitions for which NIOSH has already found that dose reconstructions are not feasible. You know, people have been adding up how much time it takes us to do a dose reconstruction and then concerned, rightly, how much more time, once you get to that point, to then evaluate a petition.

So this is what we've proposed. We have -- and I'll be glad to explain it a little bit here -- Section 83.14 is a procedure for minimizing the time required to petitions for a class with an employee's dose reconstruction we cannot complete. And the basic strategy there is we will evaluate the petition based on the information we already collected from doing that -- attempting to do that dose reconstruction. We will sort of -- there will be no additional research on feasibility for that petition. So all the information will be at hand

for NIOSH to evaluate that petition. It in effect will have evaluated the petition in attempting to do the dose reconstruction and there'll be no time lost there.

What that provision does to allow us to do this is should -- in doing the reconstruction, should we have leads that the class may extend beyond our information, the information we have. In other words, if the information we have from doing the research allows us to define a class of only so large, but we have some indication that it could extend beyond that scope, we will then on our own evaluate that issue of whether there's a greater class than the class we've defined. But we will move the petition on immediately based on the research we have in-house, which will cover that claimant who has cancer and all like-situated employees. We'll move that on to the Board so the Board can evaluate and -- one sec, Jim -- in a sense, you have a bifurcated process, that that petition will move on with that class as defined by the research we have at hand, and we will consider then, by doing additional research, whether there is a further class of workers related to this first petition who should be considered for addition to

the Cohort. Jim?

DR. MELIUS: (Inaudible)

DR. ZIEMER: Use your mike there, Jim.

DR. MELIUS: Sorry. Clarification, since I just got this yesterday I may have missed this in reading through. But if I recall right, they would still have to submit a petition, or is that not true?

MR. KATZ: That's -- the original claimant?

DR. MELIUS: Yeah.

MR. KATZ: The original claimant would have to submit a petition. It's a -- there's not much to it, but --

DR. MELIUS: Then the justification would really be the communication back to the -- that person saying that they couldn't -- it wasn't feasible to reconstruct the dose.

MR. KATZ: That's right.

DR. MELIUS: Is that spelled out in the --

MR. KATZ: It's spelled out in the rule, absolutely.

DR. MELIUS: 'Cause it wasn't on your slide and that's why I --

MR. KATZ: Yeah. No, it's spelled out in the rule, though.

DR. MELIUS: Okay.

MR. KATZ: And all they're doing is affirming that the dose reconstruction couldn't be done. That's the entire justification for the petition.

MR. ELLIOTT: But we would help them with their petition. As soon as we figure out we can't do a dose reconstruction, we're going to notify that claimant and say we need to work with you to put a petition together.

MR. KATZ: Well, they -- I mean there's nothing to do -- I mean they are submitting a petition which is -- there's nothing to do on that petition.

DR. MELIUS: My clarification was just that the four points you listed before that they would have to provide --

MR. KATZ: No, that doesn't apply.

DR. MELIUS: Yeah.

MR. KATZ: None of those apply.

DR. MELIUS: Exactly, that's what I was trying to figure --

MR. KATZ: None of those apply.

DR. MELIUS: Yeah. Okay.

MR. KATZ: Okay. And the other thing that we've committed to that you'll love is that we will convene you as often as necessary so that we can

address these petitions on a timely basis.

DR. ZIEMER: Probably we would want that to say as seldom as possible but as often as necessary.

MR. KATZ: Yes, something like that. We could work on the wording.

DR. MELIUS: Maybe we'll put in a regional rule. If the petition's from the northwest, we can do it near -- up near Washington.

MS. MUNN: Thanks a lot.

MR. KATZ: Okay. We had Board advice and public comments on the role of the Board and the Secretary. One was to limit or eliminate the Secretary's discretion to apply non-specified procedures. As you recall, at the end of the rule before the Secretary had the right to invoke such procedures as were not specified, if need be. And the Board recommended limiting the Board's role in reviewing NIOSH decisions to deny evaluations of petitions that do not meet the petition requirements. A public comment, on the other hand, recommended retaining the Board's role. So we did eliminate the Secretary's discretion -- we took away his power -- no. There are no non-specified procedures left in this rule. And we eliminated the Board's review of petitions that NIOSH decides do

not meet the minimum requirements.

Thank you. That's it.

DR. ZIEMER: Okay, let's open it up now for general questions on any of the items Ted has covered, any clarification points. We will be going through the document later in detail, but -- Jim?

DR. MELIUS: On that last point, I thought I saw in there something about some sort of an administrative review or something of a petition that's been turned down. Can you speak a little bit about that?

MR. KATZ: Yes, that's -- we asked for public comment as to whether people thought we should have an administrative review of these NIOSH decisions if these are not going to come to the Board. Now I'd just explain -- I mean the process has changed somewhat in other ways, too, because if a petition doesn't meet our requirements, we will go back very specifically to the petitioner and identify why it doesn't and provide them with guidance for what it would require to make that petition meet our requirements, and then it would have 30 days then to address that. So in a sense, part of our process is almost a check there because they have a second go at it, based on very specific guidance as to what it

would require to bring that petition up to requirements.

DR. ZIEMER: Yes, Roy?

DR. DEHART: Would you expand just a bit on the elimination of the cancer risk model?

MR. KATZ: Sure. I mean I don't know if I can expand or if I'll just be repeating myself, but the cancer risk models -- the whole purpose of the cancer risk models was to establish a benchmark, a dose level benchmark and then determine whether doses could have exceeded it. If they exceeded it, then that would satisfy the requirement that the class may have been endangered. So that's what they were in there for originally.

Now the situation is is that where we can do a dose reconstruction -- where we cannot do a dose reconstruction, I should say, we can't -- we can't cap the dose. We can't put an upper threshold, an upper limit on the dose that they might have received. And if we can't do that, then the benchmark becomes irrelevant because whatever the benchmark, whatever the benchmark's at, the dose could have been higher than that and they meet that requirement. So we would have to go through a lot of trouble, as some of you have thought through. To

establish those benchmarks isn't that simple and it would have no value, so it -- for which reason we've eliminated it. It really -- I mean the only thing it would have done is assured people that these people -- that these individuals, you know, very well could have had their health endangered, but it had no practical value.

Does that --

DR. DEHART: If I understand then, if there is a way of doing some form of dose reconstruction, you're not removing the cancer risk model. You're only removing it when you're unable to make a judgment.

MR. KATZ: Yeah, I'm sorry. If you can do the dose reconstruction, you use the cancer risk model, yes. No, this is only in terms of adding a class to the Cohort there's no value to use this -- to use cancer risk models to determine their health endangerment, that's all. Everything else is the same about how you do dose reconstruction and probability of causation.

DR. ZIEMER: I'd like to add a comment on that concept. It seems to me that if you did benchmark it in the sense that we talked about before and you found that every member of the class was way up here

somewhere but there was a number, I think under this change you're saying well, we -- this is a dose reconstruction and it fits in the other category, but you would end up in that circumstances in compensating every individual in any event, as a group. You just don't call it a Special Exposure Cohort. It's a little bit semantics, to me, because if everyone in the group qualifies under the dose reconstruction for compensation --

MR. KATZ: It's actually -- it's not quite that. I mean what we're saying is we'll do the dose reconstruction if we can cap the dose. But if we can cap the dose, it doesn't mean that everyone -- everyone who incurs that dose would incur cancer. It means we'd do the dose reconstruction based on that cap dose and it depends on what --

DR. ZIEMER: Okay, and then the -- only the cancer individuals would --

MR. KATZ: It depends -- yeah, it depends what cancer they incur whether they're compensated or not.

DR. ZIEMER: Yes, of course.

MR. KATZ: So it's a little different.

DR. ZIEMER: But it keeps them in the dose reconstruction category rather than --

MR. KATZ: That's true.

DR. ZIEMER: Yeah. Okay. Other general comments or questions on Ted's presentation?

Okay, Mark, you're making a motion like you're thinking -- and also --

MR. GRIFFON: Where to begin.

DR. ZIEMER: -- while you're pulling the mike up there -- also, Leon, if you have any questions, just chime in. Okay?

MR. OWENS: Okay, Dr. Ziemer. Thank you.

DR. ZIEMER: Right. Mark.

MR. GRIFFON: I guess -- I guess I wanted to -- to start and -- and I agree with Jim's comment. Just receiving this less than 24 hours ago, maybe I missed some nuances. But I'm trying to grapple with this notion of tissue-specific cancer sites. And there's a phrase in the prelogue (sic) here that says -- one of the examples you gave was radon progeny or uranium would only concentrate and significantly irradiate certain organs and tissues. And I guess what I was grappling with is how do you define "significantly", and especially for this -- this -- if you've gotten to this point you've already admitted that you can't even establish a maximum dose, so -- so then it further concerns me

how you establish "significantly". 'Cause while I would agree that in those two examples most of the exposures are to certain targeted organs, there probably are small fractions of dose to other organs, as well. And if we don't know anything about the intake or the exposure, we don't know how large those small fractions could be. So I think that's -- I just wanted to know how -- how you define that "significantly" and -- or whether this is like left open to this case-by-case analysis.

MR. KATZ: Well, I mean it will certainly come --

DR. MELIUS: Could you just tell us what page you're looking at 'cause --

MR. GRIFFON: Oh, I was looking on page 15 in the prelogue (sic) where it's discussed.

DR. MELIUS: Okay.

MR. GRIFFON: Not the rule itself.

MR. KATZ: It will certainly come before you case by case because the Board will see each of these petitions and the NIOSH evaluation for it, so you'll certainly get it case by case. But for example, with radon, "significantly" isn't really -- I mean the colon, there would -- you would estimate basically zero dose to the colon, regardless of not

being able to put a cap on the radon daughters exposure, for example. In practical terms, it would be zero.

MR. GRIFFON: What does that mean, in practical terms it would be zero? I mean are you saying the --

MR. KATZ: Well, meaning --

MR. GRIFFON: -- probability of causation is zero?

MR. KATZ: Meaning that if the -- if you're talking about, you know, point zero zero whatever dose, you would say zero.

MR. GRIFFON: But you don't know the -- you don't know the dose up front. That's -- that's the point, I guess.

MR. KATZ: You don't know the dose up front, but it doesn't matter that you don't know the dose if -- you don't know the dose to the lung, absolutely, which is why the lung would qualify. But you do -- you can say absolutely that the dose to the colon would be in effect zero.

MR. GRIFFON: Give your rationale for that. Your radon exposure, you have --

MR. KATZ: Let me let Jim --

MR. GRIFFON: -- particular progeny in the lung

which stay in there; they don't go anywhere else is your argument?

MR. KATZ: Let Jim pitch here.

DR. NETON: Jim Neton, NIOSH. There's a practical basis here. I mean one could argue -- we could argue that there may be atoms of radon progeny that move from the lung to the colon, but on a practical basis we're talking multiple, multiple orders of magnitude. I mean it just -- the dose would be -- I don't want to give any quantitative numbers, but it would be several orders of magnitude below that, if not more than that, so that -- you know, you have to be practical about this in a certain situation. So yes, we can't cap the dose, but it's certainly -- since the material does not concentrate at all in that organ, say in the colon, it's not --

MR. GRIFFON: I guess --

DR. NETON: -- plausible that their health was endangered, which is the other criteria. You have to meet two criteria; you can't cap the dose, and their health would have had to have been in danger. It's not plausible of health endangerment since there is --

MR. GRIFFON: But it seems like a roundabout

way without using IREP to look at the risk side of things. But --

DR. NETON: Yeah.

MR. GRIFFON: -- I mean I guess my concern is that you're admitting up front that you can't -- I -- you can't establish the dose. But then you're -- you're narrowing this to we can't establish the radon dose for this group. I guess I -- you know, those examples are okay. I'd be -- I wonder if it makes sense for such -- these theoretical examples to change this whole policy, you know, instead of having just a list of specified cancers. Because, you know, how -- I would say that, you know, if you can't establish an individual -- if you don't know -- I mean part of your criteria is you have to know at least something about the source term and the radionuclides involved to establish exposure. So you're kind of saying okay, we don't even have that baseline information. We don't have -- we can't even get that far. But yet we're confident that it's only radon that we -- you know what I'm saying?

DR. NETON: Yeah, it kind of gets into your definition of capping, I suppose. I mean -- I always have said in the beginning, I can always cap a dose and say it's less than a million rem or

something like that. I mean you can always do something like that. And in some of those situations actually that -- that disparate. I mean you could make some wild assumption as the upper limit in some of these other -- what we consider non-metabolically-involved organs, the dose would be extremely small and not even calculable probably to the millirem levels or something like that, so --

DR. ZIEMER: But you're probably going to have to have specific cases to examine. Some of these theoretical ones that we tried out --

MR. GRIFFON: Right.

DR. ZIEMER: -- you know, they're not the real live thing so it's a little hard to say how they'll come out. I think Jim and then Tony -- oh, Tony's next?

DR. MELIUS: Well, actually Tony's reached for his microphone, so I'll --

DR. ZIEMER: Tony?

DR. ANDRADE: No, I just wanted to provide another example, perhaps one that -- well, I know it's not listed either in the preamble or in the rule. Let's take a case of plutonium. You may have a petition from a person that believes that they were exposed to plutonium, have no idea as to how

much, have no records, but believes -- strongly believes that they were exposed to that. If it is plutonium, then we know. Okay? So I'm going to propose here is that we have a scientific bases already through physiological models that plutonium tends to concentrate in the liver and in the bones. And if they come forward with a brain cancer, then it is -- or other people in the class may have had a brain cancer, it's highly unlikely that that would have been the cause. And so what I'm saying is that these physiological models do exist. There is a scientific bases for making these determinations and I think what's being proposed is perfectly reasonable.

DR. ZIEMER: Jim?

DR. MELIUS: My concern -- I have to agree with Mark. What concerns me is two issues. One is that yeah, we have this scientific basis and we would say that the risk for plutonium is more likely from certain organs, but we're applying -- with IREP we're applying (inaudible) model to that, so -- and then putting a dose to that model. Here we don't have a dose. We've already said that in this situation we don't have a dose to put in that model. And I'm afraid that we're going to spend, this

Board, a lot of time trying to decide where to make the cutoff, which organ systems will be covered in these situations, which organ -- cancers of other organ systems will not be covered. And the situation -- most of the situations we're dealing with are not going to be simply plutonium or simply radon, they're going to be much more complicated. And we're going to be spending a lot of time trying to figure out, you know, well, we have more than one that we can't estimate, some that we say we can estimate, which organ -- how do we add this up without a dose term to -- even an estimate of a dose term to be able to -- to weigh in with. And I don't necessarily disagree with the simple examples, but I'm not sure how practical those will be -- how common those will be, but that when we -- if we start applying this across the board to every petition, then we're going to be making I think very arbitrary assessments in situations where we've already said we don't know the -- can't estimate the dose.

MR. KATZ: Let me -- can I just respond a little bit? This is an ability to address -- to use this when appropriate. It is not across-the-board procedure to apply. So the only situations I

imagine when NIOSH is going to apply this procedure is -- you know, you're talking about simple cases. Well, it's -- it's sort of open and shut cases where it's very clear. And for situations where you have multiple exposures and so on, you're not going to apply a policy like this, and it wouldn't be applied. You wouldn't have any specificity about tissue sites. You would only have it when you have a situation, for example, with radon where that is the only -- radon daughters are the only dose that you can't calculate. And though you can't calculate them for the lung, you can cap them for -- cap them as -- if you're going to take into account plausibility, you can cap them for other tissue sites.

DR. ZIEMER: Any other comments? On any -- not necessarily this issue, any of the issues Ted raised.

Okay. Thank you. Ted, I think you can sit down, but be on call here.

DR. MELIUS: Actually can I ask one more question?

DR. ZIEMER: Sure, you bet.

DR. MELIUS: One of our -- and I may -- again, may have missed this in the comments, but in reading

through our comments from the last time, we raised an issue about -- where we had cancer sites that were not listed as part -- not eligible for the SEC compensation, and then issues where part of a person's work history can -- could be -- those could be estimated, part would fall under -- into the Special Exposure Cohort in sort of mixed situations. If those -- in our comments we asked that NIOSH address those situations in the follow-up. Are those addressed in these regulations?

MR. KATZ: They're addressed. They're addressed in the preamble, yes. Yes, so, for example --

DR. MELIUS: Could you give me --

MR. KATZ: Yes -- no, I'm -- I wasn't going to leave you hanging, Jim.

DR. MELIUS: Thanks.

MR. KATZ: So where the doses -- where an individual has doses outside of the window for the cohort, and couple that with they have a cancer that is not compensable as a member of the cohort -- that's what you're talking about, that situation -- what you do -- what we have to do is a dose reconstruction. And what we discuss in the preamble is that we don't have an answer right now

for what do we do with that window that -- when you do the dose reconstruction they have this window, you know, for which their colleagues were added to the cohort, but because they don't have the right cancer, they can't be compensated as a member of the cohort -- they're part of it, but they can't be compensated. What do you do with that window where you can't estimate doses? And it's -- we address that in the preamble that it's a problem that we're going to need to discuss with you and it's a pretty sticky wicket because we've made this determination that we can't reconstruct dose for that window, and yet there's this individual who had that exposure, as well as the exposures that we can estimate with, and we're going to have to do a dose reconstruction for them, what do we do with that window to be able to address this problem. You know, if we can address this problem it will probably require revising the dose reconstruction rule because right now under the dose reconstruction procedures, you know, we reach a dead end, we can't reconstruct a dose. There would have to be a change to the dose reconstruction procedures.

And you know, I'd be glad to engage with the Board in the discussion of what sort of things you

might think about in addressing that situation, but what the rule says is it's not a part of this rule because it's an issue of dealing with dose reconstruction and not dealing with adding a class to the cohort.

DR. ZIEMER: Mark?

MR. GRIFFON: I just wanted to -- just a clarification on the definition on sufficient accuracy. It is when you can calculate a maximum --

MR. KATZ: Yes.

MR. GRIFFON: Can you re-- what is the --

MR. KATZ: You want me to say it verbatim?

MR. GRIFFON: Well, not verbatim.

MR. KATZ: I mean it's in the rule, but yes, it's if you can -- if you can calculate a maximum dose to the class, then you still can do dose reconstructions with sufficient accuracy. And that's of course, you know, your least preferred situation, but --

MR. GRIFFON: And just to clarify that, the maximum do-- if you can calculate a maximum dose, then those maximum doses will be used in their determination of --

MR. KATZ: Yes.

MR. GRIFFON: -- probability of causation?

MR. KATZ: Then they would have dose reconstructions based on those maximum doses versus something more accurate and lower.

DR. ZIEMER: Jim, and then --

DR. NETON: I'd just like to maybe clarify what Ted said. Not necessarily the maximum dose if we could develop some sort of a distribution, but the maximum credible dose would be used in the analysis. It would not always be the maximum dose.

MR. KATZ: But it could be.

DR. NETON: It could be, sure.

MR. KATZ: Yes, which is --

DR. NETON: But if one generated distribution, a theoretical distribution of doses, that would be the sampling that would be done to do that dose reconstruction.

DR. ZIEMER: Jim?

DR. MELIUS: I believe this is a semantic issue, but you've raised it a couple of times here is that in a class if you can do this maximum credible dose, whatever we want to call it, for any individual in the class, then the class doesn't qualify for a Special Exposure Cohort. But that wouldn't necessarily mean that the dose could be applied to everybody that worked in some -- you

know, part of the class could be eligible and part couldn't, so we could split that -- that class up, so to speak --

MR. KATZ: Right.

DR. MELIUS: -- the class -- the petition could be split into a group that could be estimated and doesn't qualify in a group that doesn't. Is that --

MR. KATZ: That's correct, and that's still in the rule. That was in the rule before and that's still in the rule as it is.

DR. ZIEMER: Okay. Thank you. Oh, Mark, did you have another item?

MR. GRIFFON: No.

DR. ZIEMER: Okay. Now what I'd like to do at this point is develop a strategy on proceeding on how we will evaluate the rule. I have a couple of suggestions, but I want to get some feedback on this. First of all, as Ted suggested, we do want to have an opportunity to step through all of the changes and identify what those are. There are a couple of ways to do this. One is to simply do it sequentially.

But the other thing that occurred to me -- and I'd like you to think about this for a minute and then we can discuss it -- would be to look at all of

the Board's own items; that is, the items that we raised, and ask how those were resolved to see if we are satisfied in a sense, if I can use that terminology -- if we are satisfied with the resolution of the issues that we raised relative to the earlier version of the rule. And then after doing that, then go back and look at all of the other items in terms of what other changes have been made.

So I'm asking the Board, do you have any preference one way or the other on how to proceed? Tony?

DR. ANDRADE: Paul, there've been so many substantial changes -- very good changes, in my opinion -- to the rule that I would suggest that we step through section by section. Some of them will be -- will require very little time. Others will address concerns that the Board raised and yet others will address concerns that were brought up by the public, and I think we will be giving due diligence -- due diligence review to all of the concerns that were brought up.

DR. ZIEMER: Richard?

MR. ESPINOSA: I kind of agree with the section by section. Also I'm kind of concerned about the

amount of time that we have to review this, as well as the public comment period. I believe the public comment period should be extended to 60 days. And also is there anything in the works about having -- in the last SEC stuff there was stakeholder meetings. Is there anything in the works for a stakeholders meeting over this?

MR. ELLIOTT: The public comment period will be 30 days. That's a Department decision and they're going to stick with that. There are no town hall meetings scheduled to deliver this notice of proposed rulemaking like there was in the last one.

DR. ZIEMER: Roy and then Jim.

DR. DEHART: In addressing your suggestion, I would prefer to see it as Tony has suggested, sequentially go through, but identify as we do clearly where the Board changes are occurring.

DR. ZIEMER: Jim?

DR. MELIUS: Just back to that point on public participation, public access, I feel we should at least go on record. I find this whole procedure to be very unsatisfactory. We are given a rule to read with substantial changes less than two days before our meeting. We are -- there is no opportunity for any members of the public to see the rule until they

got to the meeting here today, no -- and I think a lot of our -- some of our comments from before were informed by comments from the public and from the public participation. Given the major changes, I just find it very unsatisfactory on the part of the Agency to be putting such a strict time limit and to preclude any public participation in this process.

And I also was a little concerned, does the Board have enough time -- given our current planned schedule, which is to review today and then to finalize comments in a week -- for something -- which means we will have seen and looked over a rule for eight days and some of us -- I know many of us have other things to do with our time, so we're not -- let alone a chance to really discuss some of these -- you know, some of these changes.

MR. ELLIOTT: I would like to react to one part of your comment, Dr. Melius. The public has had as much -- unfortunately, as much advance notice in delivery of the rule as you all. We sent out four e-mail distributions announcing the availability of the rule. One of those was public-wide and included everybody that signed up for -- through our OCAS web site e-mailbox, callers who called in and wanted to be notified when the rule appeared. I believe that

-- Cori, correct me, but I believe that single distribution notice was very lengthy in the number of people that we touched.

I, too, share -- we're not happy that we got this put on the table any earlier than we did. You have a week from today for a teleconference. We should talk about today whether or not you feel you're going to need a second teleconference to accomplish what you need to do before the end of the comment period.

DR. ZIEMER: Okay. Wanda?

MS. MUNN: I'll have to admit, I groaned audibly when I watched 91 pages crank off my printer. But having thought about it, I recognize that we can't have it both ways. I can't have the time that I would like to have to assimilate every aspect of this revised rule and at the same time meet our I think generally-agreed criterion of expediting this process as much as possible. So I have no problem with the 30-day requirement. If we're going to expedite, then we need to expedite.

I was not as smart as Dr. Melius and did not think to bring a copy of our previous Board comments with respect to the earlier rule. If it's possible, if there's a copy of that around somewhere, it would

be helpful to me as we go through this -- I hope step by step -- to have --

DR. ZIEMER: I think we can make these available.

DR. MELIUS: I have a copy here if someone else doesn't have --

MS. MUNN: Good.

MR. KATZ: Also the comments are in the rule.

DR. ZIEMER: They are identified --

MR. KATZ: They're actually in the preamble of the rule, with responses to them, so --

MS. MUNN: I saw them, but they were not in the lump for --

MR. KATZ: They're in a lump called the section on -- the section on the Board is -- has all the comments from the Board.

DR. ZIEMER: Jim?

DR. MELIUS: Yeah, I just want to -- I think the Board's done a lot to try to expedite through the process, but mind that NIOSH has had over six months now, I believe, correct -- maybe five months to revise this rule. And to then make us expedite our review in -- whether it's two days or ten days or whatever is being expected, I think is hardly fair. We continually expedited the review of

various regulations here on one-day notice or a few days notice, whatever, going through and we're still at a point on dose reconstructions where 17 I believe have been completed and despite having rushed through a rule a year and a half ago, whenever it was. And I find it hard to believe that a change in 15 days or 30 days in the comment period, if it would help us to provide better comments -- and I think that's something we should discuss, would the extra time help us in this process -- I think hardly makes any difference in terms of the ef-- on the part of the effort of the Board 'cause we do have a duty to fulfill in terms of reviewing these comments and reviewing them thoroughly and providing as good advice as we can, and doing it in a very short time period may not make that possible.

DR. ZIEMER: I suppose each person would have to answer that for himself or herself. I know what often happens in my case is if we have 60 days, then that means I don't have to start on it for another 40 days or something and I end up using about the same amount of review time. But that may not be true of everyone.

One of the real issues is we do have -- people

do have other commitments and may not, in a very short time such as one week, be able to address this very easily. So that would be more of a concern that I would have than simply the scheduled issue could be problematic. Jim?

DR. MELIUS: But there's also the issue of us -- of the Board being able to discuss and --

DR. ZIEMER: Right, sure.

DR. MELIUS: -- respond to each other 'cause I think we do --

DR. ZIEMER: I understand.

DR. MELIUS: -- learn and modify our comments in response to --

DR. ZIEMER: Sure.

DR. MELIUS: -- other people's concerns, and some people understand parts of this much better than I do and I think it's --

DR. ZIEMER: Rich has a comment.

MR. ESPINOSA: I absolutely agree with Dr. Melius. After reading the public comments, it helps me understand and kind of refine what we're going through. And to have 30 days with the public comment and then not even a meeting in between, a face-to-face meeting in between is kind of disturbing for me.

DR. ZIEMER: Thank you. Other comments? Okay, we'll kind of keep those issues in the back of our minds as we proceed here. They may re-emerge as we go along. I do believe that we've sensed perhaps an agreement that we should --

A pause just a minute. We've lost Leon, apparently.

(Pause)

DR. ZIEMER: Leon?

MR. OWENS: Yes, sir.

DR. ZIEMER: We lost you somewhere along the line, sorry.

MR. OWENS: Yes, Dr. Ziemer. Thank you.

DR. ZIEMER: We are discussing how to proceed with the review. There also has been a brief discussion on concerns about the -- both the 30-day time period for public comment, as well as the timetable for the Board to develop its own comments.

What I'm going to suggest is that we proceed with reviewing and understanding what's in here, and we will revisit as we go -- perhaps later in the day to sort of see where we are and look at strategies for the future telephone conferences and what we think is needed for us to do our job. I think the issue of opening it for public comment for a longer

period is basically a Departmental decision, but certainly the Board members can make their views known on that item. We do need to determine at some point today how we will proceed in terms of what we think our ability is to get our comments done.

Now Rich, did you have another comment here as --

MR. ESPINOSA: Yeah, I do on -- kind of on the same subject. On Ted Katz's presentation he was talking about a -- the verification requirements. Can you explain a little bit on that? I didn't understand that?

In other words, you didn't have to be specific on the verification requirements for the SEC?

MR. KATZ: Sure, that was in the first -- that relates to what was in the first NPRM, not what's in here now. In the first NPRM we had a provision that you would have to in effect verify from the employer that they don't have the records that you are asserting they don't have, and we took that out.

DR. ZIEMER: So the burden is not on the employee anymore to --

MR. KATZ: And so, for example, with an AWE where you don't even have the employer anymore and there's no one to go to, you're not going to them.

Is that clear?

MR. ESPINOSA: Yes.

DR. ZIEMER: Are we in agreement that we would -- in terms of reviewing the document, that we would proceed then section by section?

Let me also note that the sections beginning with the summary and the supplementary information and so on, as well as the various definitions such as what is a Special Exposure Cohort, what's the purpose and so on, much of that is boilerplate information that we probably don't need to dwell on a whole lot. Also the summary of the comments is what it is, and unless you think that they have not summarized something clearly, we don't need to fiddle with that much.

It is helpful to go through the preamble and learn how they've dealt with the various issues. My understanding is that the preamble is informational, is not part of the rule. Is that correct, Ted? It does not have --

MR. KATZ: That's correct. The preamble is not the rule. The preamble is informational and does not get codified in the Code of Federal Regulations.

DR. ZIEMER: Now it certainly is conceivable that as we go through the preamble Board members

might have suggestions on clarifying issues or making things more clear, but keep in mind those items are not part of the rule but are intended to help us understand the changes that have been made. And for that reason it'll be very important to go through them section by section and ask Ted and other staff members to amplify and clarify the various changes and we have the opportunity in each case then to ask about those. And insofar as the changes show up in the rule itself, then that becomes very critical.

The rule itself then, if we could just clarify where that begins. What constitutes "the rule" -- and Ted or Larry, if you could help -- is it subpart A? Is that the beginning of the -- subpart A --

UNIDENTIFIED: It starts on page 64.

DR. ZIEMER: Okay, just ahead of subpart A is the official text of the -- it says Text of the Rule. That's the part, for which if we have specific recommendations or comments, that we would have to actually focus on. So we're talking about -- as far as the rule is concerned, pages 64 through 90, so it's approximately a 25 or 26-page rule that we're really focusing on. With a need, of course, to understand what's going on in terms of what's in

the preamble. Okay?

So what we will do, and I think we'll go ahead and take our break first. But then we will start in, section by section, to go through and start to try to understand the scope and extent of all the changes. I suppose -- I'm hopeful that as we proceed and get a better feel for what is here and what isn't here, how things have changed, that we might also develop a good feel -- aside from the sort of gut feeling we have about the short time, at least develop a feel for what it's going to take for us to get our work done. And you know, if we say for some reason that it's just going to be impossible in 30 days, in terms of our schedules and what we think the extent of our comments are going to be, then we'll just have to make that known.

On the other hand, we might say you know, these changes are all so good, we just don't have very much to do. I don't -- I'm probably looking at two extremes here, but the point is that I think we'll have a better feel for this rather than just our gut reactions right now once we sort of get into it and test the waters. So we'll proceed here for a while and see how we do before noon, and then have also an opportunity to hear some public comment perhaps

early afternoon, and that will also help us shape our thinking.

DR. MELIUS: Just schedule-wise, 'cause I thought we were going to hear about the dose reconstruction --

DR. ZIEMER: Oh, we are, yeah. We're going to do that. Do you want to do that before the break?

MR. GRIFFON: It doesn't -- Cori was making copies, so I don't know if she has them yet, so maybe --

UNIDENTIFIED: After the break?

DR. ZIEMER: Let's go ahead and take our break and, Leon, we're going to take about a 15-minute break. Did we lose you?

MR. OWENS: No, sir, I'm still here, Dr. Ziemer. Thank you.

DR. ZIEMER: Okay. We don't want to lose you on the break, so --

MR. OWENS: No, definitely not.

DR. ZIEMER: So I guess we'll leave the phone line open --

MR. OWENS: Okay, sir.

DR. ZIEMER: Okay.

MR. OWENS: Thank you.

(Whereupon, a recess was taken.)

DOSE RECONSTRUCTION REVIEW PROCESS WORKGROUP

DR. ZIEMER: Now we have on our agenda the report of the dose reconstruction review process work group. Mark Griffon is chairing that work group. Mark is going to bring us a status report today on the activities of the group. They don't have specific items for us to take action on today, but will give us an update on their activities and the outcome of their meeting yesterday. Mark?

MR. GRIFFON: Is this mike working?

DR. ZIEMER: Yes, it is. You might want to put the lapel mike on just in case you're not close enough to the other.

(Pause)

DR. ZIEMER: Okay, copies of Mark's slides were just distributed to you. Leon, you probably don't have copies unless we -- did we FAX any of these to Leon?

MS. HOMER: No, I have not.

DR. ZIEMER: Are there copies for the public?

MS. HOMER: I've handed some out and there are some back on the --

DR. ZIEMER: There are some on the tables, thank you. There are just six slides, so Mark, if you'll make sure as you go through these to at least

verbalize the points so that Leon has the benefit of knowing what you're talking about here.

MR. GRIFFON: I will. I will. Okay, this is the -- as the title indicates, a status report of the dose reconstruction working group. We decided last meeting we -- we were tasked to continue on as a working group -- or a newly-established working group to do several things on the dose reconstruction review process, and these tasks were develop draft procedures for the review process, develop procedures for case selection, develop individual task orders to be released after the task order contract is awarded. And to do this, at the last meeting we had some discussions that it might be beneficial for us to come a day early to this -- before this meeting -- to Cincinnati, to NIOSH's offices and actually ORAU's office in this case and go through their database and actual case files and have sort of our draft procedure to walk through some actual case records, case files, so that we know sort of what the review team is going to be up against when we actually start doing these. Okay?

UNIDENTIFIED: Thank you, Mark.

MR. GRIFFON: That's my status report.

(Pause)

MR. GRIFFON: All right, so -- okay. What we really focused on yesterday, we were at the ORAU offices all day, pretty much from 9:00 till 3:00 or so, and the focus was on the procedure side of things, to look at -- at the last meeting Paul had -- had put out a sort of template or a first cut of a draft for the basic review, how the contractor, along with the Board, are going to walk through a review process for the basic review of a individual dose reconstruction. And I -- I actually drafted -- and these are in draft form. We're not even ready to provide them, I don't think, to the full Board, but I modified that somewhat, added to that somewhat for a basic review and then advanced review. And then we tried to take these procedures and walk through while -- at the computers there at ORAU, walk through actual cases and -- and go through the questioning and see okay, exactly how is a reviewer going to answer these criteria that we've laid out in the RFP and in our procedures.

We looked -- we see this sort of as a part of the basic review and advanced review. I think we're going to have something -- we're going to have a report form, an executive summary form and a Board summary report. And the report form I envision as

the report that the contractor primarily -- although Board representatives will work with the contractor -- but the contractor primarily will generate and report that reviews the case.

The executive summary will just be -- just be that. It'll be an executive summary of the case review. It won't have as many details and that will probably come back to the entire Board for consideration. And then this last thing, this Board summary report is what we envisioned as the Board's report to the Agency, to HHS, and it would be sort of a summary of aggre-- an aggregate number of cases and were there any findings or concerns in aggregate from the cases that have been reviewed in that quarter, in that half-year or year or whatever that time frame we decide.

We started off our day yesterday with a briefing from NIOSH and walked through a couple of cases, final cases, cases where decisions have been made. And we looked at the databases, the NOCTS, which is the NIOSH-OCAS Claims Tracking System. That's the database and then the administrative record for each case file, and we looked at the various parts of this to see what kind of records are actually captured in these. There's a dose

reconstruction folder, there is a correspondence folder, a DOE correspondence folder and -- I'm forgetting one, there's --

UNIDENTIFIED: DOL.

MR. GRIFFON: -- Department of Labor correspondence file, so it's broken out kind of into types of documents. And within those, all the records used are captured -- all the records used for the individual dose reconstruction case are captured within those folders. Most of these are in PDF format. I think there's only a few -- the one file I can think of that's in an Excel format is the actual IREP input file that would be used to run the IREP analysis. All other forms are -- at this point are in PDF format, meaning that if a reviewer was to use this data they'd probably have to sort of hand-enter any analytical files that they might want to do. For instance, if they were going to do an internal dose assessment, the data's there, but they'd have to re-enter raw data and do their own assessment that way -- something we did talk to NIOSH about and there may be some things that they're willing to add to make the process easier for the reviewers -- to make Excel files for certain things, then the reviewers can just use them that

way instead of having to re-enter data.

Okay. And so we -- we spent most of our -- our day going through these cases and -- and finding out what was actually in these administrative records and actually how to use this -- this database and looked through this database.

Okay. The other thing we did discuss was the -- how to schedule the case reviews and the coordination of the Board and the contractor or contractors. We did talk as -- as in the past, we've mentioned this notion of having designated Board members, and this could be on a rotating basis and -- and that -- that really -- we didn't really hone in on that yet, but designated Board members that will work with the contractor, and the Board members would meet with the contractors on groups of cases prior to the presentation back to the full Board. So individual representatives from the Board designated to work on a certain group of cases. Those individual Board members would get the same materials that the contractor would get at the same time, far in advance. The contractor would proceed to do the bulk of the legwork on it, but then the Board members -- we -- we see the model as the Board members would then have a chance -- an opportunity

to work with the contractor ahead of time, before presenting back to the Board, to question the contractor on -- okay, you know, when I -- when we looked at this we -- we found these things; did you find these things, were there problems with certain aspects of this. And then we may have a case where the -- you meet with the contractor a day before a Board meeting and you go through a pre-identified set of 20 cases and we can see a situation where you may have -- you may say okay, we agree with you on 17 of these cases and we think we should present these to the Board. These other three cases we feel -- we have questions that we didn't feel -- that the contractor should re-examine further and they may take those three back and not present those to the full Board at that point so that that's sort of how we see that -- you know, that way that -- every Board member would not be involved in an in-depth review of all of the cases that the contractor's doing. It would be designated members would work on designated cases.

And then the presentation of the final review ports (sic) would go to the Board and the Board -- ultimately the Board has the consideration of the final cases, so...

We also talked about the case selection process. As we -- I just mentioned, we're talking about only reviewing cases after final decision, so we did have some discussion about how many cases would be available and when, and we compared this against the calendar and the timing with when the contractor would be -- when the contract is likely to be awarded and I have a little -- the last slide I have is a little bit of a time line on how we see this -- this going down the pike.

We talked more about case selection criteria and by that I mean site exposure, cancer type, and then our strategy for sampling and -- and we tried to work with NIOSH yesterday and we -- we still have to do some more legwork on this, but to characterize the existing -- the characteristics of the cases they have right now. As I estimated yesterday, Dick Toohey from ORAU did provide us with a query of the number of dose reconstructions by site, sorted by site, and there's about 12,000 -- a little more than 12,000 cases I believe are currently in the system. And this -- this gave us a sense -- and we further asked well, can we -- can we sample -- in the current database can we stratify this further by these other parameters, and we're still -- we're

still working through some of these things to see how we might do that. So at least we got a sense of by site where the major claims are and we're going to proceed on -- use possible other strata and how we might sample against that.

And then the final thing is develop individual task orders, and we will probably focus on -- the initial task orders we see as most urgent, I guess, would be the basic review task order, the advanced review task order and the procedures review task order. And we -- we think that we can do this in parallel so that we can have the final drafts of these task orders ready by the time the contract is awarded. And then as soon as the contract's awarded we can release these task orders so that the contractor or contractors can bid against those task orders. You know, that's -- shortening the time as best we can so that we can actually get some reviews done. I think that was it for that.

The one thing on the task orders, we feel pretty confident that the -- a lot of time and effort went into the contract itself in specifying, especially for basic review and advanced review, specif-- there was a great level of detail and specificity, and we don't think it's going to be a

major leap to go from there to actual task orders for those two particular things. For SEC petition review and the -- and for the site profile reviews, which -- I think they're still in there, they're less defined right now in the -- in the overall contract, so I think we have a little more legwork to do. And we didn't have a rule at the time when we were writing this so we -- you know.

And here's the time line I was talking about. We -- the task order -- as I understand it, as of yesterday this task order -- RFP should be published by the end of March, sometime -- maybe a little before the end of March.

MR. ELLIOTT: Could I speak to this time... I can give you some harder dates.

MR. GRIFFON: Okay. I didn't want to commit you to harder dates, Larry.

MR. ELLIOTT: No -- no, that's okay.

MR. GRIFFON: I was being -- I was being nice up here.

MR. ELLIOTT: No, and I don't want to steal your thunder, but I --

MR. GRIFFON: I was going to put hard dates, but --

MR. ELLIOTT: You should write them down

because you can hold me accountable for this because I -- we sought yesterday from the contracting officer what exactly could we say today to the Board --

MR. GRIFFON: Okay.

MR. ELLIOTT: -- about hard dates.

MR. GRIFFON: Okay.

MR. ELLIOTT: Let me just add one element to your time line. The five-member technical evaluation panel was identified and incorporated into the contracting -- the procurement, and that was done 2/18/03. It took us that long to finally get the last person to commit.

On 3/18, March 18th, we will see the synopsis of the RFP announced in the *Commerce Business Daily*. What that means is your scope of work and your evaluation guide will be presented for public viewing in that -- in the *Commerce Business Daily* as a synopsis. That'll happen on March 18th.

On March 21st the RFP -- or excuse me, May -- or April 21st the RFP will be released for bid, so they'll have 30 days to examine it and then they'll have about another 30 days and at the end of May the final proposals will be due. I don't have a date to give you there. That'll be actually determined by

the contracting officer.

MR. GRIFFON: Right.

MR. ELLIOTT: There's some -- several steps as you see here in addition to those. There's a pre-bid conference. That date has to be determined yet, and it will require the presence of the Chair and any other Board members that want to participate in that, but it's your procurement so you need to at least have Dr. Ziemer there and other Board members who want to speak to questions about your intent.

Then the due date for receipt of proposals is yet to be determined. That would happen after the pre-bid conference.

MR. GRIFFON: Right.

MR. ELLIOTT: And then there -- the due date for the technical evaluation panel report is yet to be determined. The date for the award is yet to be determined. There's a number of steps in between all of these that the contracting officer has to check off and do, so many more than you have there.

MR. GRIFFON: Yeah, yeah.

MR. ELLIOTT: But this is the critical time line.

MR. GRIFFON: This -- yeah, thank you, Larry. We -- and I had a couple of those dates from

yesterday but I was -- I didn't want to hold you to some --

MR. ELLIOTT: I wanted to make sure what we could have on the record and what we could share with the Board.

MR. GRIFFON: Okay, right.

MR. ELLIOTT: I'd also remind the Board to send in any names and addresses of potential bidders for this solicitation to Martha DiMuzio. I sent an e-mail out -- Cori sent an e-mail out last week for me. We need those by Monday in order to keep on track here. These are people you think might be interested in seeing this RFP and we'll make sure that they are so alerted.

MR. GRIFFON: And we -- and finally we also estimated or ORAU gave us an estimate that by the time of contract award or roughly therein -- or this estimate that I have anyway on this time line, there should be some 1,300 cases -- is that --

UNIDENTIFIED: Probably closer to 2,000, but they won't all be final.

MR. GRIFFON: Okay, they won't all be final, right. Right. So probably -- probably 1,300 to 2,000 cases with dose reconstructions complete. They may not be through the DOL process, but...

MR. ELLIOTT: I would just qualify that with what it takes to become a final dose reconstruction ready for your review. And of course there's the 60 days after that the claimant receives their decision for their appeal to happen, so you have to allow that 60-day --

MR. GRIFFON: Yes, and we did --

MR. ELLIOTT: -- window to expire before you could take it up as a completed case.

MR. GRIFFON: Larry, we considered that in there, yes.

DR. NETON: It's a 30-day window, just to correct that. I was wrong, I thought it was 60. It's a 30-day window for the notice of appeal.

DR. ZIEMER: Thank you.

MR. GRIFFON: And I think that's -- that's it. That's it.

DR. ZIEMER: Okay. Let's open the floor for questions, any clarifications needed. Roy? Or additional comments from others on the working group, as well.

DR. DEHART: I think the Board would be interested to know that probably all of us will have an opportunity to review these cases as they come through the contractor, working with the contractor.

And the information, as we understand it today, will be available on disk, so everyone will get a disk for those cases that they're reviewing, how many number of reviewers that we have, two or three for each cycle. And we would see this occurring on a monthly basis and it means that we each are going to have to have some time for an educational opportunity to see how those data files exist, how we access them and what they mean. So August/September we're going to be learning how to assess this.

DR. ZIEMER: Thank you, Roy. Jim, comment?

DR. MELIUS: Two -- actually two questions. One is -- and I'm not sure you can answer this, Larry, and you probably have answered it earlier, but it's this issue of are there going to be one or more than one contractor awarded and how that determination is made. I can't remember what we -- how we've dealt with this up to date, but are --

MR. ELLIOTT: You can make a --

DR. MELIUS: -- there criteria for that?

MR. ELLIOTT: You can make a multiple award based upon who bids and how you -- how the technical evaluation panel qualifies them. If there's two equally technical, capable -- if you want to make

two awards or multiple awards, you can do that under this procurement.

DR. MELIUS: And is that something the review group recommends or is -- how is that dealt with? I just...

MR. ELLIOTT: I think that the technical review group will get a charge from the contracting officer that has to speak to that. The Board has to provide some input to the contracting officer as to their desire to see that level of evaluation occur. So you need to be -- you'll need to be up front with the contracting officer that, you know, we want to see what comes forth in the proposals, and if there are equally-weighted proposals after the technical evaluation panel, we might be interested in making a multiple award. It's between you and the contracting officer at that point in time.

DR. MELIUS: And so where does this come back to the Board then, this process? I guess that's what I'm trying to...

MR. ELLIOTT: It would be after the technical evaluation panel meets and provides their information to the contracting officer. Contracting officer would then get in touch with the Chair and walk the Chair and, if you had a working group with

the Chair or however you want to set this up so that there's more than I think just one person looking at this, it would be a decision made at that time.

DR. MELIUS: Okay.

MR. ELLIOTT: NIOSH -- of course NIOSH is not going to be making that decision for you. This has to be a decision of the Board how you want to proceed with the award.

DR. MELIUS: And that's why I'm bringing it up as an issue of scheduling and where this -- we have to figure out how to fit that into the Board's schedule so we're not holding this up.

MR. ELLIOTT: It comes at -- right before -- there's a step called the best and final offer, and so there's a negotiation process when you identify the top proposer or proposers. Then you go into what's called BAFO, best and final offer, and that's at the point that the Board needs to interject do we want two, three, six, one -- how many awards do we want to make. And then you -- then the BAFO goes forward with all of those reacting, or just one reacting to provide a --

DR. MELIUS: A related procedural question concerns the task orders. Now we'll have -- according to Mark's schedule, there'll be the -- the

draft task orders from the work group around the end of May or something. Is that something -- at what point does the full Board discuss those? And then I'm particularly concerned related to the issue of the OMB review on terms of -- some point we have to come to grips with the whole issue of how do we review the interviews --

MR. ELLIOTT: Sure. Sure.

DR. MELIUS: -- and to what extent we can talk about that. And I think the plan, as I recall, was that we would do that in terms of a specific task order, and the task order would have to become a -- be a public document, I think --

MR. ELLIOTT: Right.

DR. MELIUS: -- for us to discuss it and move it forward. Is there an option for only part of that document to be public so that we could just focus on the interview section without violating whatever your procurement rules are and so how does that fit in I guess is my question.

MR. ELLIOTT: You would need to take up Board discussion of task orders after the proposals have been submitted. And I need to check on this, but it may -- maybe also after the best and final. I don't know how much a task order development in a public

forum would influence a best and final. So I'll check with the procurement office about that. I understand the dilemma, that if it's after the best and final, that gets right up close to where the award's -- it's probably a month before the award is made. That doesn't give you a lot of time.

DR. MELIUS: Okay. Then at the time you check that, could you also check about the possibility of a partial task order being discussed here 'cause -- 'cause that's going to -- that's a process to move that forward that could -- I mean the longer we get -- delay getting that started, the long -- and I think there needs to be discussion by the Board of that issue and how to handle and so forth, but I think we need to sort of understand the time line here 'cause that could -- could conceivably get -- delay that a long time and -- and could be a problem.

DR. ZIEMER: Gen and then Tony. Or --

DR. ROESSLER: It's Bob. We look a lot alike.

MR. PRESLEY: Well, I'd like to make a recommendation that the Board, as a total, be given the opportunity as soon as possible to go see what we did yesterday so that the total Board will be able to start this as soon as possible, just as soon

as we get ready and everything gets done, so -- because everybody's going to have to go through it.

DR. ZIEMER: Robert, we'll so note that. Recognize our next meeting is in Oak Ridge, so it can't happen then, and it would have to be perhaps after that.

Okay, Tony.

DR. ANDRADE: Just a quick question for Larry. Don't we have to disclose at the bidder's conference whether there will be consideration for multiple contractors?

MR. ELLIOTT: Yes. The answer is yes, at the bidder's conference you -- thank you for that correction 'cause you will have to have a -- you'll have to have an open blanket statement that it will be considered. It won't be -- you know, it's not a final commitment, but it's a consideration the Board will give to the proposals submitted, and we can make that happen.

DR. ZIEMER: Other questions or comments? Any other working group members have items they want to input? Jim?

DR. MELIUS: Just back to the issue on the review of the interviews, depending on what -- how Larry gets back to us on what the answers are in

terms of timing, I think that -- I guess in terms of the next step coming up for the working group or new working group, I'm not exactly sure how we're doing this, would be I think really to look at what some of the options are for reviewing the interviews, that that get fleshed out in some way that we can -- for now. You may have done it already, I don't -- don't know what -- I didn't hear it described yesterday, but --

MR. GRIFFON: It didn't get described.

DR. MELIUS: Yeah, so I think that would be helpful -- again, somewhat depending on what -- how -- what Larry's answer back to us is when we can openly discuss it, so...

MR. GRIFFON: Yeah, I expected it to come up when we started fleshing out the basic and advanced review, you know, that we would have to flesh out that and look at options on how that could be handled, so we will.

The only -- the only other thing I was going to add is that -- before we leave today I'll try to get hold of all the working group, maybe at a break, and see if we can schedule a conference call down the line here to meet before Oak Ridge. I think we probably need to keep this thing moving, so...

DR. ZIEMER: Okay. And we'll expect an update then at Oak Ridge on the status of this effort. Thank you.

BOARD DISCUSSION/WORK SESSION

SPECIAL EXPOSURE COHORT - NPRM

DR. ZIEMER: Any other comments on this topic? If not, we'll return now to our Special Exposure Cohort working session. And let's ask Ted to step us through -- as we go through section by section, ask Ted to identify what changes have been made in that particular section. That will help us to address these sequentially. So does everybody have their copy now of the document? I'm looking to see if there's anything on the first few pages that anyone has any questions about, the supplementary information, the statutory authority -- which is simply -- basically describes the document and why it's being prepared. The definition of the Special Exposure Cohort on page 6 --

MR. KATZ: Dr. Ziemer?

DR. ZIEMER: -- any -- yes.

MR. KATZ: I'm sorry, the part I was going to help you with -- I was going to walk you through the actual rule itself. Is that -- are you going to go through the preamble first?

DR. ZIEMER: I thought we would go through the preamble 'cause that will help us. Is that a good way to do it, Ted, from your perspective or did you want to refer back and forth?

MR. KATZ: I mean that's fine, but there's no -- there's no role for me in terms of changes. The preamble's completely different, basically because it's dealing with the comments and so on. But if you want --

DR. ZIEMER: But the preamble does explain what was done.

MR. KATZ: It does explain in response to comments what was done. What I could do -- I mean you can do it that way. Alternatively, I can walk you through the sections and tell you section by section exactly what was changed and why, and you'll capture all that section by section versus sort of issue by issue, comment by comment, which is how you'll get it in the preamble. And the preamble doesn't address other changes that weren't commented on, either. So -- so if you want to do the preamble

first, I'll -- I can step down from this now or if you want to do the rule itself first.

DR. MELIUS: I think the rule would be easier.

DR. ZIEMER: Huh?

DR. MELIUS: I think the rule would be easier, and then go back --

DR. ZIEMER: Yeah, it sounds like we can start with the rule itself and then use that as a springboard to go back into the preamble as needed. Okay.

But let me double-check. Are there any issues before that actual preamble stuff, any questions on the early part of the document? Okay.

Let's go into the rule itself then.

MR. KATZ: So at page 66 or thereabouts.

MS. MUNN: Page 64.

MR. KATZ: Well, I mean there's -- I mean this is just -- it begins with the -- yeah, the table of contents, which you probably don't --

DR. ZIEMER: Anything on 64 or 65 that anybody has questions on? Subpart A? Any questions or comments?

MR. KATZ: And just let me say then, since we're starting with 83.0, for 83.0 we just made minor clarifications and added legal citations and

there's nothing substantive changed from what you reviewed before.

DR. ZIEMER: Questions or comments on that section? The same for 83.1 and 83.2?

MR. KATZ: So 83.1, let me explain what changed in 83.1. We added explanation to this section clarifying that the SEC rule's not intended as an alternative compensation avenue for cancer claims that have received dose reconstructions and have been denied under the non-Cohort procedures, and indicate that there is a DOL procedure under 20 CFR Part 30 for a claimant to contest a finding of a NIOSH dose reconstruction. And this was a thing that the Board actually recommended we make this clarification. This was responding to the Board's comment.

DR. ZIEMER: Let me again ask, any questions on that change? It's near the bottom of 67, the last few sentences, and is response to a Board comment. No questions? Okay.

83.2?

MR. KATZ: Now this -- we've only made minor clarifications to this. We did drop a section. There was a -- in the original there was a section 83.2 that was entitled "How would cancer claimants

be affected by the procedures in this part?" and it was non-procedural and really redundant of other explanation in the rule, so we took it out to make a savings where we could.

DR. ZIEMER: Questions on that section? Okay, Subpart B, anything under definitions, 83.5?

MR. KATZ: So do you want me to tell you about some changes we made here? We revised the definition of class of employees to delete the requirement that the employees of a class be similarly exposed to radiation. All that's important is that we can't reconstruct their doses, but they don't have to be similarly exposed to be within the class.

DR. ZIEMER: Tony has a question.

MR. KATZ: Tony, sorry.

DR. ANDRADE: More of a comment, Ted. I don't know if you want to jump into this here or not, but under the definition of class of employees there is hidden in there a very important piece, and that is that one of the discussion points that we got caught up on was what happens to employees that work at multiple facilities. And in here we talk about looking at employees that have worked at one facility at a time and that have been potentially

exposed at that given facility.

MR. KATZ: That's correct.

DR. ANDRADE: Am I correct in that?

MR. KATZ: It's still -- it was in the previous version and it remains defined by a single facility, class of employees employed at a facility, not across multiple facilities.

DR. ZIEMER: Does that answer your question, Tony?

DR. ANDRADE: I didn't know if we wanted to discuss that any --

DR. ZIEMER: Well, if you have an issue on it, let's -- anyone? Okay, proceed.

MR. KATZ: Okay, let me tell you -- let's see, there are more changes in definitions, as well. Let's see, we deleted the definitions for "endangered the health", IREP and "probability of causation" since these are no longer needed, given the way the rule is now constructed. We also revised the definition of "specified cancer" to be consistent with the definition under the DOL regulation that was finalized this past I think whatever, December or -- what it was, I think it was December. And we also added a definition for "survivor" under EEOICPA since this term's used in

the rule. That's the extent of the changes to the definitions section.

DR. ZIEMER: Any questions on that section? Comments? There appear to be none.

Then Subpart C, procedures for adding classes.

DR. MELIUS: Can I just go back one second?

MR. KATZ: Yes.

DR. MELIUS: I'm catching up with you here, but the section 83.2 which in the old rule which you've deleted, I'm thinking -- I don't have any problems with the deletion, but it was helpful to have some sort of explanatory information for people. Now you can -- in terms of what their options are and so forth. Now it doesn't necessarily need to be in the regulation 'cause I'm not sure people will read the regulation, but in terms of your outreach materials and what's on the web site and so forth, I think it'd be important to include some of that same information, obviously --

DR. ZIEMER: I thought you said it was already covered in other places.

MR. KATZ: It was redundant, in effect, of other -- and it in fact confused -- you know, the reason we thought to look at it even was because it actually confused some commenters rather than

clarified things for them.

DR. ZIEMER: By appearing in this section or just in general?

MR. KATZ: By -- they were just confused by the explanation. We -- they drew the wrong inferences from the explanation we had there, too, so it was -- it was misleading to them.

DR. ZIEMER: Okay, Subpart C, Ted.

MR. KATZ: Yes, section 83.6, all we've done here is made minor clarifications. It's just English.

Section 83.7, two changes here. One, we clarified that the eligibility of one or more employees or survivors of a petition on behalf of a class, you know, is limited to members of the proposed class or their survivors. In other words, employees and survivors cannot petition on behalf of a proposed class in which they're not included -- on behalf of another class, in other words.

And second, we added -- as I discussed earlier -- a third group of eligible petitions comprising one or more individuals or entities authorized by employees or survivors of the proposed class. And that was responsive to the request from non-union advocacy groups to have the authority to petition,

as well, on behalf of a class. So we've given it as broad a possible interpretation as we could.

DR. ZIEMER: And I'm looking for questions or comments on that change.

MR. KATZ: Okay. Section 83.8 then, how is a petition submitted. We made one change, which is to eliminate the requirement for use of a petition form. We had comments saying we shouldn't require people to use the petition form, so we don't. It's voluntary. They will have to address the informational requirements of the petition either way, but they don't have to use the form that we're providing.

DR. ZIEMER: Okay, no comments on that? Larry?

MR. ELLIOTT: Ted, just so we can be specific here and be on the record, this rule does not present that form. That form is being worked up. It has to go through OMB clearance before we can actually use it and distribute it, so that's why it's not attached to this rule.

MR. KATZ: That's right.

DR. ZIEMER: But just for clarification, whatever form is developed becomes part of the rule by reference then, or is it --

MR. KATZ: No, it doesn't --

DR. ZIEMER: -- just that there is a form?

MR. KATZ: There is a form. It's voluntary -- use is voluntary.

DR. ZIEMER: Voluntary anyway.

MR. KATZ: But -- and there will be instructions, as well, for either -- whether you use the form or not -- that will be useful to petitioners.

So then hearing no more, on 83.9 there are a whole number of changes. So we eliminated the requirement for people who we attempted dose reconstructions and they couldn't be completed, they don't need to send us their report anymore. They only need to indicate the basis of the petition. That's the first change.

The second change, we eliminated the requirement that the petitioners provide information specifically related to the determination of health endangerment. That's gone, and that information, as I said earlier, is no longer useful, really.

The third change is we established these new -- which I've presented -- maximally objective requirements for the petitioners to justify their concern that it might not be feasible for NIOSH to estimate their radiation doses with sufficient

accuracy.

The fourth change is we deleted a requirement concerning the feasibility of dose reconstruction, which was the verification -- requiring petitioners to seek verification from DOE or an AWE with respect to their information on what data's available.

And fifth, if a petition's based on an exposure incident versus normal operations, we include the option of requiring the petitioner to provide evidence of the incident, although only in cases where we can't confirm the occurrence of the incident through other sources available to NIOSH. We don't think this will be very common, but those are the only circumstances where they would have to do that.

DR. ZIEMER: Yes, Henry.

DR. ANDERSON: I see that it's a proposed -- as part of the applications, a proposed case -- or class definition and that ultimately HHS will decide that?

MR. KATZ: That's correct.

DR. ANDERSON: I mean that kind of opens the possibility -- what would happen if somebody files this and then as part of your definition the person is excluded, so now you don't have somebody

proposing who's part of the final group? Is that a possibility of happening? I mean -- it would still go -- so you'd create a class, but there would be nobody in it yet because the person who's applying it wouldn't apply to anymore. Is that a --

MR. KATZ: That is possible. I mean it is possible that someone proposes a class that they're in --

DR. ANDERSON: That they think they're in but they aren't.

MR. KATZ: -- and by the time -- by the time we've done the research and so on, the class is defined -- it might exclude them. That's true.

DR. ANDERSON: But then would it still go forward as a class?

MR. KATZ: It would still go forward. I mean once -- the point of a petition is to initiate the consideration of a class that should be considered. So whether the person who petitions and thinks they're a part of the class initially, whether they ultimately end up -- when I -- let me clarify. They would -- their petition -- they would be part of a class that would be considered in any event. What might happen, though, is that if they petition to be part of a class and we go into it, we do the

research and what we find is in fact there are two classes here, there's a class for whom we can do dose reconstructions and a class for whom we can't do dose reconstructions. And that individual that petitioned might fall, in reality, into the class for whom we can do dose reconstructions and hence we may establish a class, add a class to the Cohort that does not include the initial -- original petitioner. That petitioner would still have his/her class considered, but the result of that consideration may be that they're not added.

DR. ANDERSON: But it would go forward to be part of it. It wouldn't be --

MR. KATZ: Oh, it would go forward.

DR. ANDERSON: Since the person isn't in it who applied, it then is a denied petition?

MR. KATZ: No, no. So that class would go forward and be considered by NIOSH, it would be considered by the Board, considered by HHS and so on. But there might be -- what I'm saying is it might be two classes.

DR. ANDERSON: Yeah.

MR. KATZ: And that person may not be in the class that ultimately gets added.

DR. ANDERSON: So you could add a class for

which you don't yet know that there's anybody in it, other than theoretically. I mean there's nobody who's applied who would be part of --

MR. KATZ: Right, nobody's applied, but we would know that there were people who did the work that's part of the class definition.

DR. ANDERSON: Okay.

MR. KATZ: Right? In the jobs and so on, so we'd know that --

DR. ANDERSON: It wouldn't be -- I wouldn't want you to go to all that work and then, because somebody's excluded --

MR. KATZ: Right.

DR. ANDERSON: -- it then gets dropped.

MR. KATZ: Right. But I mean you could create a class where no one ever incurs cancer, as well.

DR. ANDERSON: Yeah.

MR. KATZ: And you never end up compensating anyone because no one incurs cancer.

DR. ZIEMER: Jim and then Tony.

DR. MELIUS: I haven't read through the new rule enough to know what -- how you're handling this, but in that particular case then who -- who can represent that class in terms of should there be a -- an appeal or some sort of a problem? Is it the

person that gets turned down -- appeal or what -- you know, who's sort of monitoring what's going on and who has any sort of right to appeal or deal with issues related to that petition?

MR. KATZ: Well, the petitioner -- as I said, the petitioner's petition goes forward and they can -- they can appeal their -- they can appeal their -- you know, their handling by -- the results of the petition process. They can appeal it -- they're not excluded -- they're part of the process, they're still the petitioner, they will -- if they don't like the outcome, they can appeal it.

DR. MELIUS: Yeah, but what if there's another part of the outcome that somebody else might object to who's not a party to the original petition? Do you split up the class in such a way that...

MR. KATZ: So --

DR. MELIUS: -- that you have a -- but -- you split it up, but you limit it in some way, but you don't limit it in a way that affects the original petitioner, and -- and you -- say you -- assume you're correct, that that petitioner should be turned down, that their dose or the class they're proposed and that -- at least part of that class can be reconstructed? It seems to me it just gets --

MR. KATZ: So then the petitioner who's out -- I mean in this case, the petitioner then -- again, the adverse outcome would be affecting the petitioner and they would appeal. And then the other class that you created that would be added to the Cohort, I'm not sure what they'd be appealing.

DR. MELIUS: Well, what if there's also, in essence, an adverse decision related to some other part of that class -- proposed class? I just don't understand the --

MR. KATZ: Well, I mean --

DR. MELIUS: -- procedure of the thing here.

MR. KATZ: I mean it --

DR. MELIUS: It gets very complicated.

MR. KATZ: I mean you wouldn't -- it's not complicated, I don't think. It's -- the possibility is that you have identified a class, identified two classes rather than one, one class for whom you can do dose reconstructions and one class for whom you can't. And in that case, if the petition is adversely affected, they can appeal the decision. Whether they're adversely affected or not, they can appeal the final decisions of the Secretary.

DR. MELIUS: Okay.

MR. KATZ: But I think the class that's added,

if that comes about, they're not going to be -- any appealing.

DR. ZIEMER: Tony.

DR. ANDRADE: I would just like to comment that on the other side of this issue that multiple petitions can be filed by different people or groups of people, and what HHS can do is actually combine petitions if they're similar in nature.

DR. ZIEMER: Okay, thank you. Roy?

DR. DEHART: If NIOSH has evaluated a claimant's dose and you're unable to establish whether or not a -- you can't do a reconstruction -- dose reconstruction, that individual will not automatically be entered into a petition. Is that correct? That individual must file specifically.

MR. KATZ: They must submit a petition is true. We will -- when we -- when we determine that we can't do a dose reconstruction, we will directly encourage the individual to submit the petition and provide them with the form to submit the petition. So -- I mean I envision they will always submit a petition, having found that they can't have a dose reconstruction. But --

DR. DEHART: You've answered my question.

MR. KATZ: Yes.

DR. DEHART: They're not -- they're not just hanging out there.

MR. KATZ: No, they're not hanging out there, and we will be encouraging them -- I mean that's a class we want to deal with, right, because we know we have a problem.

DR. ZIEMER: Other comments?

DR. MELIUS: Just --

DR. ZIEMER: Yes, Jim.

DR. MELIUS: Back to my previous confusing question, 'cause I'm confused. I guess the example I come up with would be that if we're going to do this organ-specific cancer, that the petitioner may have one cancer, they may get allowed. But what happens to all the people that have kidney cancer that get turned down who aren't really represented? There's never -- there's not an appeal. They would have to then petition as a new class in order to appeal the -- the rejection by the Board 'cause there may be additional information, whatever. I mean it just -- I don't know. I think we'll have to work -- see how this works out through -- procedurally, but it seems to me it's potentially problematic.

DR. ZIEMER: Are there other changes in this

section, Ted, that you want to highlight? As you proceed, be sure to identify any of these that are related to Board comments.

MR. KATZ: Yes. There are no other changes to this section, but -- yeah, okay. So I don't think any of these were -- well, the Board also discussed this issue of verification.

DR. ZIEMER: Right.

MR. KATZ: I'm not sure it was in there, their comments.

DR. ZIEMER: I think Henry has a comment.

DR. ANDERSON: Yeah, do you foresee, as these begin to accumulate, that now a -- another person files, they don't know that they're actually part of a class. Will you be able to up front identify that -- that they might -- so that you don't go through all of the attempting to reconstruct, only to find out after the fact that you can't?

MR. KATZ: That they're part of a class?

DR. ANDERSON: Yeah.

MR. KATZ: No, I think -- we're going to be able to -- DOL will -- I mean it won't even come to us.

DR. ANDERSON: Okay.

MR. KATZ: DOL will identify them as part of

that class.

DR. ANDERSON: So we won't --

MR. KATZ: So it won't even come to NIOSH as a -- for a dose reconstruction.

DR. ANDERSON: So once you define the class, it'll be sufficiently tight that they'll be able to spot that when somebody comes in who doesn't know they're part of --

MR. KATZ: That's right. It's very -- it'll be very precise, so they won't know they're going in as a member of the Cohort, but they'll be treated as a member of the Cohort by DOL.

DR. ANDERSON: Yeah. Okay.

MR. KATZ: And then it's entirely possible -- we're going to do as much as we can to get the word out to the claimant population that we've added a class to the Cohort. We're going to work that as hard as we can, but in any event, even if they don't know, if they incur cancer, they make a claim, they'll be treated as a member of the Cohort.

DR. ZIEMER: Jim.

DR. MELIUS: Yeah, I'd just like to point out, I think you've also done some reorganization of the way the information is presented about short term over incidents of exposure, you've reworded some of

that, I think, and at least moved it around organizationally within this section on petitions.

MR. KATZ: Okay, I'm not saying I didn't gerrymander paragraphs or whatever, but --

DR. MELIUS: I'm not accusing, I'm just pointing it out, Ted. People -- people on the Board should take a look at that and see if it's clear --

MR. KATZ: Okay.

DR. MELIUS: -- if we're going to -- something we need to consider commenting on 'cause it confused me when I first read it.

MR. KATZ: Okay. So are we --

DR. ZIEMER: Let me just ask for clarification there. Simply because of the position in the document, it may look like something was deleted when it was simply moved or -- is that the kind of thing you --

DR. MELIUS: Well, I think as they -- in terms of adding some of these new criteria and information, they've sort of reworked some of this stuff, and I haven't really had a chance to read it in detail to know if it's better or worse. But it confused me when I first read it.

DR. ZIEMER: Yeah, Leon, I guess we lost you and you're back?

MR. OWENS: Yes, sir, Dr. Ziemer. Thank you.

DR. ZIEMER: Okay. I feel like a fisherman, I'm losing him, but he's back on the line.

MR. KATZ: Okay, so --

DR. ZIEMER: Thank you, Jim, for that comment.

MR. KATZ: -- now we're on section 83.10. Is that right? Yes. It's 83.10, if a petition is -- I suppose I -- let me just --

MR. GRIFFON: Can I just go back to 83.9?

MR. KATZ: Oh, yes, I'm sorry.

MR. GRIFFON: Sorry. On page -- I'm looking at these two sections, it's on page 75. It's I think number (2)(iii) and (iv) --

MR. KATZ: Yes.

MR. GRIFFON: -- on page 75. And at the end -- I guess I'm just a little -- okay. And I -- I haven't walked this across with our past -- with the past proposed -- proposal and the -- and our Board's comments actually so, you know, I'm flying blind a little here. But my concern is that are we putting the hurdle a little too high for information to come -- or for -- for these petitioners? And specifically I say in section (iii) there at the end of it, it says that they -- if they have a health physicist or other individual with expertise in dose

reconstruction documenting the limitations of existing records on radiation exposure at the facility as relevant to the petition and -- and this is where I have a little concern maybe -- and specifying the basis for finding these documented limitations might prevent the completion of dose reconstructions for members of the class. I wonder if the first part wasn't sufficient enough that they get ex-- you know, we're asking -- I'm just concerned that we're putting a high demand on the petitioners when they may not have access to as much relevant information. They -- they may have a very valid petition, but they can't meet that second half because they don't have enough facts to, you know...

And then the same goes for section (iv). I'm not sure what a scientific government agency is, and then I'm also worried about published in a peer-reviewed scientific journal, specifically because of that last clause. It says "and also finds that such information might be essential to produce such estimates." Again, that language makes me think that geez, these -- you know, I don't know of many peer-reviewed journ-- art-- journal articles that are going to be that specific for that subgroup of workers at a certain facility that they can be even

used, so would it even be sub-- and I know of a lot of published documents, from DOE, for instance. I don't know if that's a scientific government agency. I would assume it would be -- sorry, editorial comment -- but you know, would, you know -- I'm just concerned that a couple of these phrases make it look to me like the burden of proof here is higher for these potential petitioners. I don't know if that's different than the language previously included or not.

MR. KATZ: Let me respond to those. One, number (iv) wasn't there. That was actually put in there at the behest of the Board, and it's a either/or -- the -- it's not only peer-reviewed. The DOE would come in under this. They don't have to be published in a peer review. They could also be a government report, unpublished -- you know, in a journal or whatever. It wouldn't be published. A scientific report by a government agency would also qualify, so it's either/or, not a both together requirement. Right. So to cover those DOE --

DR. ZIEMER: Part of this --

MR. KATZ: -- reports that you're discussing.

DR. ZIEMER: Ted, I think part of this is a wording issue. I think a scientific government

agency is not a recognized -- it may even be an oxymoron, who knows? But I think the intent here is that it's a scientific or technical report from a government agency, so the wording at some point will need to be clarified there. And then I believe Mark is asking whether or not a peer review report has to in fact include the conclusion that the information is essential -- let's see, how is this worded --

MR. GRIFFON: Finds that such a -- finds that such information may be essential to --

DR. ZIEMER: Well, it may very well be a peer-reviewed report that's not directly addressing the issue of dose reconstruction, but might in fact contain information very important to this issue or a special cohort --

MR. GRIFFON: Yeah, or --

DR. ZIEMER: -- so it may not make the conclusions that you're talking about here per se.

MR. GRIFFON: Or it may not be completely class-specific, you know, it may -- but it may be tangentially relevant to the --

DR. ZIEMER: Right, right, but I --

MR. GRIFFON: -- topic, something like that --

DR. ZIEMER: -- suspect this is more of a wording issue. I think the intent of both the

Agency and the Board is the same here. We may need to do some word clean-up at some point here.

Jim, you have a further comment?

DR. MELIUS: Yeah, actually continued down on that page, bottom of page 75 over to the top of page 76, this is in relationship to the exposure incident thing I was speaking to earlier. And two comments, I think one's a little confusing because this is a section that talks about what needs to be in the petition and you actually have a requirement for exposure incident that only -- as I understand it, is only triggered if NIOSH is unable to obtain records or confirmation of the exposure incident from other sources. And then you require -- have a requirement that the petitioner -- I'm not sure who has to provide this, but someone needs to provide either the medical evidence that one or more members of the proposed class were -- had medical evidence of acute overexposure or there's an affidavit from two employees who witnessed the incident. And I don't recall if that -- those -- those were requirements from the earlier, but it seems out of place here when we're talking about what's in the petition. It seems to be more informational and it also ought to be fleshed out in terms of what is

confirmation of the incident 'cause seemed to me the technical reports, government reports, so forth could be qualified in sort of what the process -- but it seems to me that this isn't part of the petition. This is part of the evaluation of the petition.

MR. KATZ: No, it actually --

DR. ZIEMER: Ted, can you address that?

MR. KATZ: It actually -- I mean if -- if an incident's being alleged that -- and we go out and we can't find any information to indicate that the incident occurred, that's when we come back to the petitioner and they have to demonstrate in effect, one way or the other, that the incident -- they have information to suggest that the incident occurred.

DR. MELIUS: Well, I have two points. One is that this is included in a section, what information must a petition include, so it's in the section on the petition and you're requiring information that they can only get after NIOSH has evaluated the petition and is unable to confirm --

MR. KATZ: No, I mean --

DR. MELIUS: -- that such an incident took place.

MR. KATZ: It's being -- I mean NIOSH would

have to go out and determine whether that incident occurred, if there are records on it and so on --

DR. MELIUS: I -- I --

MR. KATZ: Right.

DR. MELIUS: I'm not --

MR. KATZ: That's not the NIOSH -- that's not the NIOSH evaluation of the petition as a whole, that's the evaluation of -- we're evaluating one issue which is --

DR. ZIEMER: It may be a sequential thing.

MR. KATZ: -- is this a documented incident.

DR. ZIEMER: The original petition may not have that information 'cause they don't know at that point --

MR. KATZ: Right.

DR. ZIEMER: -- that NIOSH can't confirm it. Is that what you were saying?

DR. MELIUS: Exactly. Yeah, exactly, so this is --

MR. KATZ: Right, it would not be in the original -- in the original petition --

DR. ZIEMER: And NIOSH would go back and ask --

MR. KATZ: -- but we would come back to the petitioners --

DR. ZIEMER: -- them to provide additional

information.

MR. KATZ: That's correct.

DR. MELIUS: Right, and there's a section 83.11, what happens if it does not satisfy requirements, that -- it seems to me it's just out of place and it's going to be confusing to a petitioner. They're not -- you know, why is it in the section on what should be in a petition?

MR. KATZ: Because -- because we have to -- we have to confirm first that we have -- that we have an exposure incident.

DR. MELIUS: Right, and that's the evaluation of the petition.

DR. ZIEMER: Jim is asking why shouldn't that paragraph be under 83.11, what happens -- it's sort of like what are the next steps.

MR. KATZ: Well, it could go under 83.11.

DR. ZIEMER: I think the point's been raised --

MR. KATZ: I'm sorry.

DR. MELIUS: Yeah.

DR. ZIEMER: -- and at some point we might --

DR. MELIUS: And the comment --

DR. ZIEMER: -- do that.

DR. MELIUS: -- is that it should go in there.

MR. KATZ: It should go in 83.11, okay.

DR. MELIUS: Yeah.

DR. ZIEMER: So it's a matter of where it is in the structure here in a logical sense. Okay.

Tony and then Henry.

DR. ANDRADE: I agree with Dr. Melius. However, I think it's a simple addition to 83.11 that says that further information contained in this particular section may be requested during the period of time that NIOSH assists with the development of a petition.

DR. ZIEMER: It's readily fixable. We don't need to dwell on it at this point. We're trying to identify issues.

DR. ANDERSON: Yeah, that was the only thing I was going to say was rather than require the person as a part of the petition to go out and find support, I would just put here that if they allege an incident, they need to know that as part of the validation they may want to -- to do that, so --

MR. KATZ: Right, we're just letting them know that we may come back to them.

DR. ANDERSON: Yeah.

MR. KATZ: And I agree, 83.11 is --

DR. ANDERSON: That a --

MR. KATZ: -- another place is --

DR. ANDERSON: -- claim must be --

MR. KATZ: -- probably better for this.

DR. ANDERSON: -- substantiated with -- with other -- with somebody else, as well.

MR. KATZ: Section 83.10 then, if we're -- if we can -- if we're moving on. This is a new section, so you didn't have it in your old rule. And it's intended to clarify the distinction between the role of petitioners in providing sufficient justification for a petition and the role of HHS in determining whether or not to add a class to the Cohort. Some members of the public are under the impression that meeting the petition requirements -- the petitioner was proving that the class -- making the case that the class needs to be added and that's not -- that burden is not on the petitioners and really not within their means on their own, in normal circumstances. That's the role of the Board and NIOSH and we'll be doing a lot of research and so on to address those.

DR. ZIEMER: So this is not a change so much as a clarification.

MR. KATZ: Yes.

DR. ZIEMER: I mean it's an addition, but it's a clarification --

MR. KATZ: It is.

DR. ZIEMER: -- of roles.

MR. KATZ: It is, but it responds to really confusion we heard from the public on this.

DR. ZIEMER: Okay, 83.11 then?

MR. KATZ: Section 83.11 there are a number of changes. First of all, this and the following section were split out of the original 83.10. We wanted to separate the procedures for dealing with inadequate petitions from the procedures for notifying interested parties of petitions that qualified for evaluation. There's a notification component. We wanted to break that out of it 'cause it's cumbersome the way it was. And more clearly explained the way it is now, I think.

The second thing we did is we no longer require, as we discussed, the Board to consider and recommend the disposition of petitions that NIOSH finds do not meet the basic requirements.

And the third change, and we've discussed that I think already, we indicate that NIOSH will provide guidance and assistance to petitioners in addressing the deficiencies of their petitions.

Those are all the changes for 83.11.

DR. ZIEMER: Do we have comments on this

section? There appear to be none. Okay, let's go ahead then --

MR. KATZ: Okay.

DR. ZIEMER: -- to 83.12.

MR. KATZ: 83.12, we simplified the provisions concerning NIOSH/Board interactions on the development of evaluation plans. The Board's involvement in evaluating petitions inherently provides for the Board to review the NIOSH evaluation and provide NIOSH with related recommendations if more research is needed and so on. It was really unnecessary.

DR. ZIEMER: Comment? Here's Henry.

DR. ANDERSON: Recognizing this is going to go on over time, let's say a petition comes in and they haven't met their -- you know, the criteria, so it's -- it goes back or it's basically denied. If somebody else comes in at a later date with a similar petition, what would you do then?

MR. KATZ: Well, it would depend on whether they brought forth new information or not.

DR. ANDERSON: Okay.

MR. KATZ: But if they came forward with the same information that wasn't sufficient, it would get the same result.

DR. ANDERSON: But you would evalu...

MR. KATZ: Yes.

DR. ANDERSON: Okay. What are the -- I mean my point really was, it wouldn't be a precedent thing, that a precedent has been made -- I mean, for instance, if somebody said there was an event and you were unable to get multiple people and then subsequently somebody comes along and says they found somebody --

MR. KATZ: Right.

DR. ANDERSON: -- because it was denied earlier, you wouldn't --

MR. KATZ: We wouldn't --

DR. ANDERSON: -- just summarily be dismissed. You'd actually --

MR. KATZ: No, no --

DR. ANDERSON: -- go through and look at what's in it.

MR. KATZ: But that's new information, yes, and then moreover, we would get back in touch with the original petitioner, as well.

DR. ZIEMER: Tony?

DR. ANDRADE: Henry, I think that's covered under 83.11(c).

MR. KATZ: Yes, based on new information.

That's correct. Thank you, Tony.

DR. ZIEMER: Any other comments on 83.12?

DR. ANDERSON: I mean my -- my point was, the petitioner -- the subsequent petitioner may not know it's new information.

MR. KATZ: Right.

DR. ANDERSON: For instance, a subsequent petitioner may file that there was an incident. It's a different person filing, and now all of a sudden -- they didn't know the first person. The first person didn't know them and so there's has to be an integrating function at NIOSH rather than we've looked at this incident. We couldn't --

MR. KATZ: I see what you're saying.

DR. ANDERSON: You see what I'm saying?

MR. KATZ: Right, right. We'd have to put two and two together.

DR. ANDERSON: So that's still one person and they --

MR. KATZ: Right, or one and one, as it is.

DR. ANDERSON: -- don't know the others exist, and as long as somebody in fact will go through it and look for that versus you get back to the person and say you need to find somebody else to verify this and they say we can't, now you've denied two

that if you --

MR. KATZ: Right, in other words -- I mean we need a tickler system --

DR. ANDERSON: Yes.

MR. KATZ: -- so that we know when we're getting the same allegation.

DR. ANDERSON: Yeah.

MR. KATZ: By affidavit. Yes.

DR. MELIUS: Can I just go back to clarification on that issue, 'cause I think it's relevant here. When you say confirmation by affidavit from two employees who witnessed the incident, does that include the petitioner if the petitioner witnessed the incident? I mean that's...

UNIDENTIFIED: Two others.

DR. ZIEMER: Right, you're not --

DR. MELIUS: Is it two others?

DR. ZIEMER: You're not specifying who the two are, are you?

DR. MELIUS: Yeah, I'm just --

MR. KATZ: We're not specifying who the two are. I think you'd read that as confirmation, meaning of the petitioners, by two individuals, so I think that would be read as two individuals in addition to the petitioner, yes.

DR. MELIUS: Two in addition to --

MR. KATZ: The petitioner.

DR. MELIUS: See, I would read -- you could read it that -- if it's a labor union, say, that put it in, a representative put it in who would not have witnessed, but if you have a person who witnessed who's the petitioner, why do they need to get -- why do you have to have three? Is the criteria two or three, I guess is --

MR. KATZ: So I think you'd read this as the criteria is three.

DR. MELIUS: I disagree with that and we'll talk about that later.

DR. ZIEMER: It's probably not fully clear here which it is. Whether it's two or three, it needs to be clear.

DR. MELIUS: Clear, and I think we need to talk about what's --

DR. ZIEMER: Right.

DR. MELIUS: -- given -- situation.

DR. ZIEMER: Okay, thank you.

DR. MELIUS: That's a pretty big burden for an incident.

DR. ZIEMER: Then perhaps in that context one could ask about sort of legal frameworks for what is

needed to establish something in terms of witnesses.

DR. MELIUS: Yeah, yeah. No, it's a...

DR. ZIEMER: And I don't know what the answer to that -- I always thought it was two or more, but --

DR. MELIUS: Yeah.

DR. ZIEMER: Well, two or more -- three, as much as you want. Okay. Mike here.

MR. GIBSON: What if, just as Jim brought a labor organization or something or trying to make the petition and it's for say old AWE site or something to where there's not -- there might not be witnesses around yet, it may be for survivors?

MR. KATZ: I'm sorry, can you just run that by me one more time?

DR. ZIEMER: Yeah, it's an issue of what if there aren't witnesses around. Is that right, Mike?

MR. GIBSON: Like a labor organization brings forth a petition for a facility and it's from years ago and there may not be survivors that are readily available to verify that they witnessed the event, it's mainly for survivors --

MR. KATZ: And so the labor union is bring it forward with -- on what basis, because survivors told the labor union that an incident occurred?

MR. GIBSON: Correct. And then say you guys go back and you try to look for two or three witnesses and maybe they -- you know, you can't find them based on it was an old facility, it's been gone for years.

MR. KATZ: All right, well, this -- clearly -- clearly they would not -- the survivor would not qualify as a witness.

MR. GIBSON: No, I'm asking -- this would -- this could preclude them from -- this could eliminate them from becoming a special cohort.

MR. KATZ: It could -- it could preclude them from making the case that the incident occurred if there are no records and only survivors are asserting that the incident occurred, that's correct. You're right. That's what it says.

DR. MELIUS: But just to elaborate on that, but this is just for the purposes of qualifying. If there were say six widows or whatever that, you know, had -- you know, knew that their spouses had reported this or whatever, if there was sort of credible evidence from them, would -- couldn't that be evaluated in some way? I mean they -- do they -- this doesn't automatically make them a Special Exposure Cohort. This is just to qualify, and I

would think that a less stringent requirement could be put in here and then there'd be an evaluation of that, is this a -- are these credible accounts of -- of what happened, is it sufficient, it's hard to --

DR. ZIEMER: It's almost like how do you handle what might in courts be called hearsay. It's removed from the direct evidence --

DR. MELIUS: Yeah.

DR. ZIEMER: -- and sometimes that can be established as being credible --

DR. MELIUS: Right.

DR. ZIEMER: -- depending on the situation.

DR. MELIUS: Because it's a consistent story, you know.

DR. ZIEMER: It may be an issue that will have to be dealt with --

DR. MELIUS: Yeah.

DR. ZIEMER: -- in some way.

DR. MELIUS: Yeah.

DR. ZIEMER: Thank you for raising that point.

DR. MELIUS: Yeah.

DR. ZIEMER: Okay.

MR. KATZ: Okay. Where are -- sorry, where are we?

DR. ZIEMER: Well, let's see, that --

MR. KATZ: Are we on 83.13 now?

MS. MUNN: We're on 83.13, yeah.

MR. KATZ: Okay.

DR. ROESSLER: Did we do 12?

MR. KATZ: Yes, I think we did.

DR. ROESSLER: Can we go back to 12?

DR. ZIEMER: Hold on then, I think Dr. Roessler has an item on 12.

DR. MELIUS: I don't think we did 12.

MR. KATZ: Oh, no, we didn't do 12. I'm sorry. Oh, yeah, we did. We did -- at least I spoke about 12. You may not have commented --

DR. MELIUS: I missed it, too.

DR. ROESSLER: I just now looked at something that I think I want clarification on and that's the difference under 83.12 between (c) and (d). I mean I see the difference, but I guess I would like an example of when (d) would be acted upon rather than (c). Can you give me some circumstance where the NIOSH may initiate work to evaluate a petition without going to the Board?

MR. KATZ: Yes, I certainly think -- I mean it depends really just on the coincidence of timing that we'll want to get to work on these petitions as quickly as possible. And whether we have a Board

meeting scheduled for 45 days hence, I don't think we want to wait that Board meeting to propose to the Board our plans for evaluating that petition. We would just --

DR. ROESSLER: You'd start on it and then it would come to the Board after --

MR. KATZ: We'd trundle on and when we'd see what the Board -- we'd tell you what we're doing, but wouldn't hold it up for --

DR. ROESSLER: Okay, good.

MR. KATZ: -- for the Board, so I think that's all -- I think that's all that's intended there.

DR. MELIUS: Would you -- but you wouldn't publish a *Federal Register* notice at that point, or what's the --

MR. KATZ: Excuse me?

DR. MELIUS: I guess you would -- I guess you would -- no, I take it back. I guess you would. It just wouldn't be accepted by the Board yet.

MR. ELLIOTT: We would publish a *Federal Register* notice indicating what the Board is going to look at --

DR. MELIUS: Yeah, that's true. Okay.

MR. ELLIOTT: -- and there would be perhaps petitions that we'd already started work on and

petitions that just recently come to us before the *Federal Register* notice went out and we hadn't started work.

DR. MELIUS: Yeah, okay.

MR. KATZ: Okay. So we -- forward, 83.13? So first change here is we made the determination of health endangerment contingent on finding that it's not feasible to conduct dose reconstructions. So in the prior rule, those -- analysis of health endangerment was parallel with whether you could reconstruct doses. It doesn't make sense in this situation. We're just -- if -- if we can't reconstruct doses, then we make the health endangerment determination. It has no value otherwise since if we can reconstruct doses, that's the end of the story -- and recalling what health endangerment means here.

And we -- secondly, we clarified the criterion for finding that dose reconstructions are feasible, and we've discussed that. And we provided other guidance and we've discussed that, concerning that.

The third change is -- we've also discussed to some extent, which is we included provisions to allow for a determination that it's not feasible to estimate radiation dose that is specific to one or a

limited set of cancer sites.

The fourth change we made here --

DR. ZIEMER: Ted, could you -- specifically for the Board and for the record -- tie those different items to the sections here that are before us so we have that in the record? If you wouldn't mind going back to the beginning.

MR. KATZ: No, I wouldn't. I wouldn't, that'd be fine. Each change you want --

DR. MELIUS: Yep.

DR. ZIEMER: Each of those changes, I think it's important in the record that we be able to link that to sections here.

MR. KATZ: Okay. So -- so change one was that we made the determination -- we made the determination of health endangerment contingent on finding that we can't estimate doses, and that is -- is found under -- right, under section -- these are hard to follow, as you can tell, because --

DR. ZIEMER: That's why I'm having to put you on the spot, because --

MR. KATZ: But it's under --

DR. ZIEMER: -- it's also hard for us to tell.

MR. KATZ: Right, it's under section -- look at number (2) --

DR. MELIUS: Page 80.

DR. ZIEMER: Page 80.

MR. KATZ: -- how should -- page 81, this is the area, how should the class be defined, and if you turn the page to 82 -- wait, 81, the bottom of 81, item number (3), if it is not feasible to estimate with sufficient accuracy radiation doses for members of the class as provided under paragraph (b)(1) of this section, then NIOSH must also make the following determination as required by statute: Is there a reasonable likelihood that such radiation doses may have endangered the health of members of the class. So that's where it specifically makes it contingent. Is that -- is everybody with me where that is? It's the bottom of 81 and the top of 82, if we have the same...

Okay? And then change number two was the criterion for finding that dose reconstructions are feasible, and those are found under -- on the page 80, beginning with (b)(1), and continuing through the bottom of the page. Actually continuing through the top of page 81.

Section (iv), Roman numeral four, is the last part of this section.

MS. MUNN: Comment?

MR. KATZ: Okay.

DR. ZIEMER: Question -- Wanda has a question.

MS. MUNN: Yes, I had a comment. Again, it's semantics only. At the bottom of page 80, item (iii), when reading through that, my first impression was that the wording was very dismissive of dosimetry and area monitoring data. Again, I guess it's how you define necessary. I guess my thought was -- I can understand why we would want to say that those data are not the defining factor in estimating, but to say that it's not necessary is almost as though you're saying who needs it. And I guess --

MR. KATZ: Well, it's specifically not necessary to estimate the maximum radiation doses that could have been incurred, which is different from saying not necessary to do a very focused dose reconstruction.

MS. MUNN: I understand. That's why I said it's purely semantics. It's just that it struck me as being dismissive of the data.

DR. ZIEMER: I think the suggestion here is there might be a way to word this that takes away that connotation, without changing the -- Jim?

DR. MELIUS: I don't know how you want to

handle this procedurally, but it seems to me this section has three major issues that we need to spend some time discussing. Two of them are old, one's new. The old ones are this issue of not feasible to -- with sufficient accuracy -- dose reconstruction, which again we've been provided with a very vague definition of that and with very little guidance in the draft regulation. Personally I have a lot of problems with that and continue to, but I think we need to discuss that.

The second is the top of page 81, this organ-specific determination that's going to be made, which is new and again is described very, very briefly and without any guidelines. And I think we need to spend some time talking about that.

And then the third issue is the health endangerment where there's been a major change from the approach used before to a way of defining class by duration of work and two -- or duration of exposure at a -- an exposure incident, and I think we need to spend some time discussing that -- the adequacy of that. I don't know if we want to do it now or just keep going along, but I'd like to raise those points.

DR. ZIEMER: My intent here during this morning

session is to identify, as you have just done, the issues that we want to revisit in depth. And by walking through this and seeing the changes and then doing what you just said, we can flag those items and then once we're done sort of reviewing the whole thing, then we can spend time on the issues that are of major concern to the Board. I think -- rather than try to solve them on -- as we're going through here on the first cut. Is that agreeable with every...

DR. ROESSLER: Could he go over the three again and point out exactly where they are?

DR. MELIUS: Yeah, the first one is -- in the order they go through is the -- starts on -- near the top of page 80, and that's the whole issue of when is it feasible or not feasible to estimate a dose with sufficient accuracy, and there's been a change in that and that -- I won't editorialize at this time.

The second issue is on page -- the top of page 81. It's a relatively -- it's a major change, but described very briefly and that's the organ-specific issue.

And then the third issue is the issue of health endangerment, which really starts on 81, section --

paragraph (2) and goes over into page 82, for the most part, I believe, which is the health endangerment which is being talked about how do you define a class. Well, they're talking about in terms of duration of work or duration of exposure at a exposure incident -- or incidents.

DR. ZIEMER: Ted had defined -- or had identified two of the changes.

MR. KATZ: Yeah, so the third change --

DR. ZIEMER: The third one.

MR. KATZ: -- Jim and I are a little bit out of sync, but the third is on the top of page 81. That's that one that Jim -- one of the ones Jim just raised, the tissue-specific --

DR. ZIEMER: The tissue-specific organ issue.

MR. KATZ: So that's change number three. Change number four is -- we've omitted the use of IREP, so you can't find it in here. We're not using cancer risk models.

And change number five is health endangerment, which Jim also mentioned, which begins on -- where I had identified it for you before, begins on the bottom of 81, number (3), and continues through the next page until you get to item (c) at the very bottom of page 82.

DR. ZIEMER: Could you repeat that again? Where does that begin?

MR. KATZ: I'm sorry. So it begins on the bottom of 81, item (3).

DR. ZIEMER: Item --

MR. KATZ: Item (3) at the very bottom of 81, it begins "If it is not feasible to estimate".

DR. ZIEMER: Yeah.

MR. KATZ: And it continues through till you get to item (c), which is another -- so this addresses the discrete incidents versus the default health endangerment definition.

And that covers it for this section in terms of changes for section 83.13.

DR. ZIEMER: Comment? Mark, comment?

MR. GRIFFON: Sure, I have -- it's more specific I think and I think we've identified the right issues in this section so we're going to come back to them --

DR. ZIEMER: Something you want to flag at this point?

MR. GRIFFON: Huh?

DR. ZIEMER: Something you want to flag at this point?

MR. GRIFFON: Well, I just had a -- a note of

comparison for this definition of sufficient accuracy as defined in this versus on page 13 in the preamble. I wanted somebody to interpret a sentence for me there where it says basically hence -- about halfway down the page it says (reading) hence for the purposes of a compensation program a dose estimate is sufficiently accurate if it is reasonably certain to be at least at high as the highest dose that could plausibly have been received.

And that wording is slightly different -- a little more confusing to me, actually, than the wording in the regulation itself. And I wondered if there was -- if they meant exactly the same thing or if I'm reading something wrong.

MR. KATZ: Well, they do mean the same thing.

DR. ZIEMER: Or at least intended to.

MR. KATZ: And the rule is what's binding.

DR. ZIEMER: Point noted. Okay. Let's go ahead then. Where are we, at section --

MR. KATZ: 83.14.

DR. ZIEMER: -- 83.14.

MR. KATZ: This is a new section. And this is what I discussed, this is a section to deal with petitions arising when we cannot complete a dose

reconstruction out of that situation. And I've discussed the provisions of it already. I don't know if you -- I don't think you want me to reiterate --

DR. ZIEMER: The whole section is new.

MR. KATZ: Entirely new --

DR. ZIEMER: Let's just see --

MR. KATZ: -- that's right.

DR. ZIEMER: -- if the Board has any questions on it or comments at this point, items to flag.

Apparently not at the moment. Let's go ahead, 83.15?

MR. GRIFFON: Everybody's thoroughly confused.

MR. KATZ: Okay.

DR. ZIEMER: Deals specifically with --

DR. MELIUS: Does anybody -- I just feel like we need to flag that section and come back to it. I'm confused by it and I -- but I think we can do it better after we've talked about some of the other issues.

DR. ZIEMER: Thank you. Okay, 83.15, Ted.

MR. KATZ: 83.15, we did -- there are three changes here. We clarified that the Board can consider information it considers appropriate in addition to the petition and the initial NIOSH

evaluation report, and that's authorized specifically in EEOICPA.

DR. ZIEMER: And that --

MR. KATZ: That was a public commenter who interpreted the rule as it was written before to prevent the Board from considering such information, although the rule back then said that the Board could tell us to go do more homework.

DR. ZIEMER: Okay. And that's showing up in which part of 83.15?

MR. KATZ: 83.15 --

UNIDENTIFIED: (d).

MR. KATZ: -- (c). (Reading) (c) In considering the petition the Board may obtain and consider additional information not addressed in the petition or in the initial NIOSH evaluation report.

DR. ZIEMER: Wanda has a question or comment.

MS. MUNN: And it may have absolutely no bearing here, but as I was reading this and thinking in terms of having petitioners appear before the Board in open meetings, the question arose in my mind whether there were any privacy issues involved in that process that we should be considering, or whether there was any way around that particular mode.

DR. ZIEMER: Can any of the staff -- the question had to do with privacy issues and petitioners appearing before the Board.

MR. ELLIOTT: If the petitioner is a claimant and wants to talk about their claim, they can do so at their own volition. However, if the petitioner wants to talk about others that are in the system, we can't talk about that. So we would have to preclude that discussion and not hold that kind of a discussion with a petitioner in a public forum. I think, unless --

MR. KATZ: Yeah, I'm just assuming -- I mean we haven't really thought about this situation you're raising, that a petitioner has private confidential information to provide, but most certainly the petitioner could provide that information confidentially to us. The Board could have access to that information and so on. So I mean we can make provisions for -- to address that, but obviously we would protect privacy for public sessions with the Board, but...

DR. ZIEMER: Keep in mind the earlier version of the document, it appeared to the Board that the petitioner was appearing before us in a kind of hearing mode.

MS. MUNN: Yes, yes.

DR. ZIEMER: Whereas this has softened considerably with the idea if there is information that the petitioner wants to bring orally to the Board, they're welcome to do that. It's not a hearing.

MR. ELLIOTT: Let me add that in the petition, if there is information that's submitted and it's Privacy Act-related information, we will protect that and that -- you know, the petition will be summarized to the Board in a fashion that won't reveal the confidential information.

Secondly, if the petitioner wants to -- again, what I said earlier, if the petitioner wants to talk about their individual claim and the demographics associated with that that's Privacy Act-related, they could do so. But we're -- we, as a staff and as the Board members, are not going to engage in a back-and-forth discussion with that person about their particular claim. They can speak about it, but we can't react and speak back to them about it, if I'm clear. I hope I'm clear in that regard. Or question them about it, I guess.

DR. ZIEMER: Jim?

DR. MELIUS: One thing we need to work on down

the road -- one is sort of a procedure and a set of -- how the information goes back to the petitioner explaining this information so it's not -- you know, doesn't come as a surprise at the meeting.

Secondly, and this may -- this is just a clarification and I may have missed it in some earlier section, but this talks about how do we get our decisions -- Board's recommendations to the Secretary. I presume that the petitioner will also be advised of those or it would be sent to them in some way at a -- it doesn't say it in this section and it -- I'm hoping it says it in another section, or at least it should say it someplace.

MR. KATZ: ... Board's recommendations. I -- frankly, I can't tell you whether I wrote that in or not, but --

DR. ZIEMER: Well, the Board's recommendations, first of all, are public. Beyond that --

MR. KATZ: It would send it directly to the --

DR. ZIEMER: -- there's certainly nothing to preclude the Board from individually transmitting a decision to a petitioner.

DR. MELIUS: Yeah, I mean just -- agree they're public, but the petitioners may not be here. By the time they become -- it becomes publicly available --

I mean it just would be nice to have a provision in here that the -- NIOSH will notify the petition, and it may already be in here. I don't -- I'm not...

MR. ELLIOTT: Well, I don't think it's there. I don't think that is there. I think what is here is that once the Secretary makes a decision, 83.16 says the Secretary will notify the petitioner, as well as the Board, et cetera.

MR. KATZ: But at that point the petitioner will get --

MR. ELLIOTT: But your point is, whatever the Board's deliberation is, that needs to be transmitted back to the petition, so yeah.

DR. ZIEMER: But keep in mind, the Board's decision or the Board's recommendation is not the decision.

DR. MELIUS: Correct.

DR. ZIEMER: It's a piece of information the Secretary uses in making the final decision. Just as the staff's input would be weighed.

Yes, Roy.

DR. DEHART: As I read this with regard to the petitioner addressing the Board, it will be by invitation, so if you should have 100 petitioners, the Board could control that number, since it would

be by invitation. Is that correct? Is that a correct assumption?

MR. KATZ: I don't think we would preclude the petitioners from coming to any -- we wouldn't preclude any petitioners from coming to a Board meeting.

DR. ZIEMER: Yeah, the rule says we would invite any petitioner, does it not?

MR. KATZ: Yes.

DR. MELIUS: Yeah, but what I was trying to make before, we should have a procedure so that the petitioner understands, you know, how the -- how the process works so they know --

DR. ZIEMER: We can control the scheduling of that since the invitation would say come to this meeting if you wish to present additional information -- I presume.

DR. MELIUS: And I would think there would be a procedure where they would -- there would be a time set aside, you know, at the same time the Board is discussing that petition or the NIOSH staff and so forth so that they can -- if they wish to speak to the Board, they wouldn't wait till the end of the session or --

MR. ELLIOTT: I think the language here is

flexible enough for the Board to interpret it as you see fit. You may -- "invite" may mean invite comment, written comment. It may mean if you can attend the Board meeting, you can attend and present your written comments. You know, "invite" means, as I read it here, we want your input. If you come, that's one way. If you want to write it, that's another way.

DR. MELIUS: And I guess all I was saying, it's not -- doesn't have to be in the regulation, but we ought to have proced-- work it out and let everybody know.

DR. ZIEMER: Other comments? Anything else in this section, Ted?

MR. KATZ: The other two changes are we eliminated -- and it relates to what you said, Dr. Ziemer. We eliminated the use of the term "evidence". We didn't want -- the Board commented about this not being an adjudicatory forum, in effect, and we also eliminated -- that was change number two.

Change number three was we eliminated the term "consensus", which was -- it was used to characterize the recommendations of the Board. It was confusing to the public what that meant and was

unnecessary, so we eliminated it.

DR. ZIEMER: Henry?

DR. ANDERSON: Yeah, I just -- again, this may be subsequently in a procedural issue, but just given the track record of us getting things a day or two before the meeting, this thing saying that the person would be -- or petitioner to -- invited to also comment on the petition and NIOSH evaluation of findings, will there be a minimum amount of time? Will they get the findings? Will the findings be part of the notice of the meeting so there'll be a minimum of a two-week -- somewhere there needs to be -- not just it'll be at the meeting, but they need to know what your findings are that are going to be discussed so that they could -- they may decide not to come because you're saying this is a fine petition and we're going to recommend it. I'm just -- I don't know if you need it here, but I think we want to be sure that the petitioner gets notice with sufficient time to, one, be able to decide what they want to do rather than have it come up and they don't really know what's going to be here.

MR. ELLIOTT: It is a procedural issue that we need to put in place. Hopefully -- I think everybody agrees, we want to get into a meeting

cycle that is practical and appropriate and not so rushed. Traditionally and typically and -- we're supposed to have a *Federal Register* notice out 30 days in advance of your meeting. Now I'm not -- I've been not doing too well at that, as you know, because we've been meeting so frequently and in such a rushed fashion. But that 30-day -- if we can achieve that 30-day *Federal Register* notice, you know, there's things that have to happen in order to make that be put into play that would trigger notifying the petitioner, as well as the Board, as well as the public, about what's going to happen at a meeting.

DR. ANDERSON: I don't think it needs to -- my question is should this be in the rule or is this just something we'll establish, and I'm just saying when we do establish it, the 30 days certainly would be sufficient. But that's my only concern.

MR. ELLIOTT: It's something for procedural development here, not -- not in the rule.

MR. KATZ: And we have discussed that very issue. It wasn't unthought of.

DR. ZIEMER: Okay. Any other items on 83.15? How about 83.16?

MR. KATZ: 83.16, there are a number of changes

here. We clarified that the Secretary will take into consideration the NIOSH evaluation, the Board report, and they also take into account information presented to the Board in its deliberations. This is -- the Board recommended HHS clarify that the Secretary is not relying solely on the Board recommendation. This was -- this came out of a recommendation that you made to us. Do I need to find that for you or --

DR. ZIEMER: It's in paragraph (a) of 83.16.

MR. KATZ: Right. Change two is we revised the reporting provisions to report all decisions to the Secretary at this time, including affirmative decisions to add classes. We had a public comment suggesting that we add this, so we have.

DR. ZIEMER: That's item 83.16 --

MR. KATZ: That's --

DR. ZIEMER: -- (c), is it?

MR. KATZ: Yes, it is, at the bottom of (c), and particularly that was raised -- before, as we had it, we would only be notifying affirmative decisions after Congress had acted. But the comment that we received was people may want to have a chance to interact with Congress who were affected by the decision, and so agreed and we added it.

Let's see, the third change is one I've discussed, which was -- so you can't find it 'cause it's not there, but we eliminated the Secretary's discretion to employ procedures and consider factors not specified in this part.

DR. ZIEMER: Tony has a comment or a question.

DR. ANDRADE: I think this is the only part of the rule I became a bit confused on. Referring back to 83.11, therein it states that if a petitioner -- if a petitioner -- well, a petitioner will receive guidance in developing relevant information, et cetera to -- to propose or to put together a petition. And after 30 calendar days from the date of notification of this section of -- well, after 30 days of review, NIOSH will notify the petitioners of its decision to evaluate the petition or its final decision that the petition has failed to meet the requirements. It goes on to clarify that based on your information, NIOSH may reverse this decision.

However, in 83.16 it looks like -- or it appears that either the Secretary is the one who bears this burden on the notification and/or it is really not final. There is no final decision because a petitioner can actually submit in writing information that either they believe that factual or

procedural errors have occurred in the evaluation of their petition.

Now question number one is, how in the world is the petitioner going to know whether factual or procedural errors have occurred? So what I'm asking for is a kind of a claimant-friendly explanation for that.

And then finally down towards the bottom of 83.16 it doesn't give a date or time period for which -- during which the Secretary has to respond to the claimant or to the petitioner, as is done so for NIOSH in 83.11. So all of this is a bit perplexing for me.

MR. KATZ: This -- they're really quite separate. 83.11, if we decide the petition doesn't go forward, it's never evaluated, it's never -- never comes to the Secretary. The Secretary doesn't make any decisions on it, so it is us who --

DR. ZIEMER: That's a final decision on the evaluation --

MR. KATZ: That's a final decision.

DR. ZIEMER: -- not a decision --

MR. KATZ: On whether --

DR. ZIEMER: -- on the --

UNIDENTIFIED: Merits.

DR. ZIEMER: -- on the merits. It's -- right?

MR. KATZ: That's correct. It's a final decision that the petition didn't --

DR. ZIEMER: It's a decision that the petition itself was not adequate to be evaluated.

MR. KATZ: To be evaluated, so that --

DR. ZIEMER: So it's before all the other stuff. The petition is inadequate, period. There's no Board input at that point, doesn't go to the Secretary. That's --

MR. KATZ: That's right.

DR. ZIEMER: In that sense, it's final.

MR. KATZ: That's correct.

DR. ZIEMER: Except that there is a remedy.

MR. KATZ: Right.

DR. ZIEMER: Something's missing, so come back with more information.

MR. KATZ: That's right.

DR. ANDRADE: Okay. So in fact this is actually another opportunity for the petitioner to have a case reviewed.

MR. KATZ: No.

DR. ANDRADE: No?

DR. ZIEMER: It's only that the petition didn't satisfy the requirements of a -- it isn't a --

MR. KATZ: Right.

DR. ZIEMER: -- valid petition at that point. Is that --

MR. KATZ: It's only -- that's right, it's not a petition at that point. It's only -- this is only a remedy for people whose petitions have been evaluated.

UNIDENTIFIED: Is that 83.11, Tony?

DR. ANDRADE: No, I'm back on 83.16.

UNIDENTIFIED: They're talking about 83.11.

MR. KATZ: Right.

DR. ZIEMER: 83.11 is --

DR. ANDRADE: Okay, let's say -- let's say a petition has been denied. NIOSH has made the decision that it doesn't rise to the standards that we have defined.

DR. ZIEMER: I don't think the petition is denied. Is that correct?

MR. KATZ: That's right, the petition is --

DR. ZIEMER: What's denied is the petition doesn't meet the requirements of a petition. It's not even -- it's only been evaluated to see if all the information's there that's needed and so on.

MR. KATZ: That's correct, so --

DR. ZIEMER: Like did you fill in all the

blanks on the form.

DR. ANDRADE: Right, and that's clear, and they have -- NIOSH will assist in putting together a proper petition. Okay? But then within 30 calendar days, NIOSH will come back with a decision on whether or not that petition will be -- a decision on that petition will be final. All right?

DR. ZIEMER: Whether -- they make a decision --

MR. KATZ: In 30 days --

DR. ZIEMER: -- they're going to evaluate it.

MR. KATZ: Right.

DR. ANDRADE: Okay, whether it will be evaluated. If the choice has been made not to evaluate it, it appears that in 83.16 the petitioner has another opportunity to present the case directly to the Secretary.

MR. KATZ: No, no, it's not --

DR. ZIEMER: 83.16 only deals with evaluated petitions.

MR. KATZ: 83.16 -- the Secretary is proposing and transmitting decisions on petitions that have been evaluated, section (a) there, and then provides those petitioners 30 days. So it's only those petitioners for petitions that have been evaluated that are in this basket here in 83.16. It is

completely segregated from 83.11. It's only those petitioners for petitions that have been evaluated by NIOSH, evaluated by the Board, the Board has made recommendations and they've come to the Secretary. At that point the Secretary evaluates all this information, makes a preliminary decision, communicates that to the petitioner and the petitioner then has the opportunity to contest the Secretary's decision -- proposed decision.

DR. ANDRADE: Okay. I think I understand the nuance there.

DR. ZIEMER: It may be that since this led to some confusion there that maybe there is some wording that needs to be added to clarify those two cases, and so you've flagged something that -- if it's confusing to the Board, it'll be confusing to others.

DR. MELIUS: Yeah, I think some of the sub-headings I've noticed throughout the document are a little bit confusing if you look at them, like outcome of a petition. Well, thinking about the petition as it comes in, not -- and really this is an evaluated petition. I don't know if we've come up with a name for it yet, that's the problem.

DR. ZIEMER: Okay, Tony? Yeah. 83.17, role of

Congress, that's spelled out in the -- you haven't changed --

MR. KATZ: It's spelled out, but what we did do -- we did make a change, which is we reduced from 20 to five days the time allowed for HHS to report to DOL the results of any Congressional action, or lack thereof, concerning the Secretary's decision. So this is an action by Congress. This is -- we had a public comment saying you don't need 20 days, and we agreed that we could --

DR. ZIEMER: It shortened --

MR. KATZ: -- we can do it in less time.

DR. ZIEMER: -- your own time. Questions on that? This affects the staff there.

83.18?

MR. KATZ: We made changes. We added provisions to the section to specify that the Board would -- it wasn't in there in the -- although no one commented on this, but it was not in the rule, the first NPRM, but that the Board would advise the Secretary in these cases and that members of the class would be provided opportunity to contest such decisions.

DR. ZIEMER: And that's 83.18 item (3), I believe -- or it's --

MR. KATZ: I'm sorry, so it's --

DR. ZIEMER: -- (b)(3) -- (b)(3). It's on the very last page. Correct?

MR. KATZ: So it's (b)(3) and (b)(4).

DR. ZIEMER: And (b)(4).

MR. KATZ: Those are new.

DR. MELIUS: Just for clarification, does this section or this modification happen before it goes to Congress, simultaneous with it going to Congress, what's the --

MR. KATZ: This is a -- this is not a decision to add a class to the Cohort.

DR. MELIUS: Right.

MR. KATZ: This is for modifying or...

DR. MELIUS: After Congress. So you're saying the Secretary, after Congress has not acted, I guess, then the Secretary can then modify?

MR. KATZ: This is for -- this is for a class that's already been added to the Cohort.

DR. ZIEMER: And you later find you can do dose reconstruction --

MR. KATZ: We later find a cache of records -- this is a hypothetical situation here, it's not one we know what will happen, but -- and we find a cache of records that we didn't know existed that lets us

reconstruct doses for a class of workers for whom we couldn't before because no one knew the existence of this information. So --

DR. MELIUS: Okay.

MR. KATZ: Is that --

DR. MELIUS: No, that clarifies it.

MR. KATZ: Okay. Thank you.

DR. ZIEMER: Other comments? Okay. Now we've been able to flag a number of items that the Board will wish to consider in further depth. We're all ready for a break. It's the lunch hour, so we're going to recess till 1:30. At 1:30 when we reconvene we'll -- again I'd like to remind folks, particularly if you weren't here during the opening of this session this morning, that our intent is to have the public comment period at 1:30 rather than at 4:00 so that the Board will have the benefit of any input from the public that might be of use as we deliberate on the proposed rulemaking.

Also a reminder to sign in and register your attendance, if you haven't already done so.

Any other housekeeping announcements, Cori?

MS. HOMER: Hold on just a second.

DR. ZIEMER: And Leon, take a lunch break.

MS. HOMER: Don't leave valuables in the room.

DR. ZIEMER: Don't leave valuables in the room.

MS. HOMER: And if there's anything that's been presented that the Board or the audience doesn't have a copy of, please let me know.

MR. GRIFFON: And what about our valuable notes on the rulemaking, can we --

MS. HOMER: I think you can leave those.

DR. ZIEMER: We can leave them. Okay. Thank you. We're recessed till 1:30.

(Whereupon, a recess was taken.)

PUBLIC COMMENT PERIOD

DR. ZIEMER: I call the meeting back to order. As indicated this morning when we discussed the agenda, it's my intention to move the public comment period up so that the Board could benefit from comments and discussion by members of the public, so we'd like to move to that now. I have received -- too late, Bob -- I have received three, now four names of individuals who wish to comment.

We'll just take them in the order that they signed up, beginning with Evelyn Cofelt. Evelyn is -- identifies herself as a claimant and she is from Missouri. Evelyn, are you prepared to proceed?

MS. COFELT: My name -- good afternoon. My

name is Evelyn Cofelt. My husband was Chris Davis, who worked at Mallinckrodt for 15 years --

DR. ZIEMER: I'm sorry, is this mike on?

MR. PRESLEY: I don't believe it is.

UNIDENTIFIED: Maybe it needs to be lowered.

MS. COFELT: Maybe I had it up too high.

UNIDENTIFIED: That's good.

DR. ZIEMER: Okay, try again.

MS. COFELT: Hi, my name is Evelyn Cofelt and my husband was Chris Davis, who worked at Mallinckrodt in St. Louis, Missouri for 15 years and died of lung cancer, so I'm going to turn this mike over to my daughter 'cause I get too emotional. Thank you.

MS. BROCK: Hi, I'm Denise. She's emotional; I'm nervous.

DR. ZIEMER: And this would be Denise Brock --

MS. BROCK: Denise Brock.

DR. ZIEMER: -- for the record, also from Missouri.

MS. BROCK: Yes. And this is a narrative that my mother has written, so if it's okay, I'm just going to read this.

(Reading) I would just like to take the opportunity to say a few things. My husband's name

was Christopher Davis. He was employed by Mallinckrodt Chemical Company, (inaudible) Street, St. Louis, Missouri. He worked there from 1945 until 1958. In 1967 my husband was diagnosed with lung cancer. That day our whole family's world turned upside down. The world and our lives as we knew them were never the same. This cancer was catastrophic for our entire family.

My husband had his left lung removed and could no longer work. I cannot even begin to tell you the emotional and physical distress that this caused him. He was in the hospital repeatedly. Our family spent many holidays, including Christmases and birthdays, in hospital rooms. When my husband was able to be home, he was on oxygen. He could barely walk from one room to the next without becoming winded.

I had to juggle working every day, raising two small children who were six and seven at the time of his diagnosis, with trying to be at the hospital with my terminally ill husband. And even though I held a full-time job, we eventually lost our home and I could no longer afford to pay tuition for my two younger children to attend Catholic school, nor pay a baby sitter to keep them for the long hours I

had to be gone. I had no choice but to relocate.

I have an older daughter, Sharon, who at the time of my husband's diagnosis was newly married and had two small children of her own. I had to move to Lincoln County, which was about an hour from St. Louis. I moved onto property that she owned next door to where she lived. That daughter had to carry the burden of watching her younger brother and sister -- that would be me and my brother; we weren't very good, either -- while I worked and went to the hospital with my husband.

I was worried about Denise and Chris, even when they were in school. Their father was dying and I was hardly ever home. They were uprooted from their home, friends and school. I was exhausted. This was a long, horrible illness. He suffered tremendously.

His cancer spread into the right side. He later developed leukemia. He had an obstruction of the superior vena cava and the inferior vena cava. He would be up at night in so much pain. His legs eventually turned black. They looked tarred. He had to wear these elastic stockings, and when I would take them off of him, his skin would just rip off. The doctors were going to amputate both legs.

All of this affected his self-esteem. He felt emasculated and he was very frightened. At this time there was no hospice. There was no home health care, nurses or cancer counseling. Eventually my husband was told that there was nothing more that could be done.

My youngest daughter, Denise, was a senior in high school, my son Chris a junior. Bills were piling up and I had to work, so my son decided that he would quit -- I'm sorry, that he would help. He insisted on quitting school to take care of his father while I worked through the day. Then while I was at home at night, both kids worked. I even got a job at the hospital that my husband had been frequenting to try to be close to him.

On April 27th, 1978 while I was at work, Denise was at school, my son was home with his father. I received a call from Chris stating that his dad wasn't breathing and he had called an ambulance. He said that his dad had been lying down on the couch and sat straight up, clutched his chest, reached for those stockings and fell back. My husband died in our son's arms.

To this day I feel so guilty that I couldn't find a way to be in two places at once. If I would

have been home my son wouldn't have had to had that horrific experience.

My son then went to his sister's school while I waited with my older daughter at the hospital for my husband's body. My son went directly to Denise's classroom and she was told that her father had just died.

This happened two weeks prior to her graduation and just a few weeks prior to her getting married. My husband didn't see any of that.

That afternoon when we came home from the hospital, some of our furniture was knocked over. There were remnants of paramedics in the house. I even had to get rid of the sofa that my husband passed away on -- too many memories.

Mallinckrodt did this to my family. It isn't just the loss of a loved one, it's the loss of a family, a home, life experiences for everyone involved. It's financial devastation. I will be 80 years old in April. I live on Social Security and up until a month ago I worked full time. My health will no longer permit me to do that. I've had a quadruple bypass and I am in poor health.

My husband gave all that he had to that company and this government. He was one of the cold war

warriors, or were they victims? I'm tired and I have worked my whole life.

Originally I thought that this compensation would bring some quick relief. There's nothing quick about it. And trying to come up with medical records and employment records, many of which have long been destroyed, just makes a program that is rough justice even harder. It's like reliving those early years all over again.

I received a letter stating that dose reconstruction could take months, even years. Do you think that I should work until I'm 95 or 100 waiting to see if I might get compensated?

DR. ZIEMER: Thank you for presenting that. I'd like to ask if any of the Board members have questions for Denise or for her mother, or comments? And Denise, do you have additional items that you want to bring or would you like to wait?

MS. BROCK: No, I'm okay.

DR. ZIEMER: Okay.

MS. BROCK: And I scribbled all over mine because as I was sitting here, I took notes, so kind of bear with me -- and then I've read hers, so I don't guess I need to introduce myself.

Today I have a few comments to make, as well as

some issues or questions that I would like to raise with the Board. First of all, I wanted to let everybody know that I've talked to over 700 people in reference to this, and I can't call everybody. So as I told Mr. Elliott, I had to actually send letters out, so I bought a copy machine and my whole family helped me staple and stuff envelopes and whatever it took and we got the letters out. And since I've been here, my daughter -- my youngest daughter said she had 150 calls, which I don't know if she just means the phone won't stop ringing, or she actually had that many. And that's just -- basically the letter was stating -- updating what the last meeting was and me coming here and to that effect.

I've also been in touch with some local unions, and I actually put together a packet that I sent to them and it consisted of a summary of this program -- because I understand there's subcontractors that are covered under this -- and I sent a flyer. I did like a flyer for them to send to their members, as well as the bill that was reintroduced into Congress. I also sent a fact sheet and a frequently-asked question brochure, a Paducah toll-free number -- what else did I put in there -- oh,

and a list of the -- over 300 facilities. So I'm assuming that there's going to be a lot more claims generated. I bet you guys are real happy about that.

And I would also like to state that while I was at the South Carolina meeting, two more Missouri workers or claimants passed away, Don Sheats* and Tom Bruning*, and they passed away while waiting for their claim to be processed. Now their spouses have the extra burden of refiling these claims, and it's not an easy task or a priority after burying a loved one. And because so many of these workers are dying and because claims are getting letters from the Department of Labor stating that it could be months, even years, for a dose reconstruction to be completed on their claim, I started videotaping them.

They wanted their stories to be heard. Many of these men, my father included, were paid above average scale for the time to carry out the -- excuse me -- to carry out the government's mission producing atomic warfare. They were expected to work in secret, and most did, carrying their secrets to the grave. These men represented themselves as common men with not-so-common destiny. Ironically,

the government's efforts to produce a powerful weapon supply after the atomic bomb, took some of the very lives they intended to save.

And to the letter that it could take months, even years, to complete dose reconstruction, as I believe I stated at the previous meeting, these people do not have months or years. We assumed this would be quick justice and there's nothing quick about it.

And I'm kind of going over some of this -- and my mom, like most of these claimants, is in her seventies. And the problem goes beyond time. I believe that workers from Mallinckrodt downtown plant were exposed to things that they were never monitored for -- I know that, actually -- and I imagine there still hasn't been a site profile completed yet.

I understand that NIOSH is doing all that they can do, but again I must ask, when does dose reconstruction become not feasible? In a situation where you have workers exposed to things that they were never monitored for; and in that same situation there is documentations that workers were grievously over-exposed, and in one particular case 34 workers over-exposed for a year and nobody told them; and

when it's impossible to use coworker data because people had multiple job titles; and due to the lack of monitoring for all radiation exposures, just as a lay person I would assume that this would be just a few reasons to state that dose reconstruction would be beyond difficult, if not impossible, and definitely not feasible.

And I think most of you know that I'm interested in Mallinckrodt becoming part of the SEC status, and I've read through the notice of proposed rulemaking and, as I said, it was 91 pages and I have no background for this. And I took it in as well as I could and it did help today I think when you did the summary. I mean it helped inform me somewhat, but I feel that I have to go back and maybe explain to some of these people and I -- I can do the best I can, but one thing I would like to ask, and I don't know if it's possible -- please, if you could come to St. Louis possibly and do a public hearing or something where maybe somebody that knows what they're talking about could do this instead of me, and maybe have time for public comment. I just -- we have so many people there that have a lot of questions.

And I know I'd asked Larry, too, if -- I

understand you have a radon model and I think we had talked about having a radon smoking model because I did research on -- I think we talked about that being synergistic with the smoking.

And then the questions I wrote down, under section 83.7, page 72, who can submit on behalf of a class of employees. I guess maybe I just didn't understand this. There's just me, and if I want to do that for my mom, I'm assuming I can do that -- I'm guessing. But what if I've got like all these people calling me and they don't have any help. Can I do that? Can I do that on their behalf? Do I have to do a class or person by person, or can I even do it?

DR. ZIEMER: Denise, do you want to go through your questions and then have them answered, or we can take --

MS. BROCK: How -- it's up to you, however you would prefer to do it.

DR. ZIEMER: Maybe if there's some simple responses, obviously we can't deal with the case itself here in the public forum, but in the general sense of --

MS. BROCK: Of petitioning, I mean can I petition for these people?

DR. ZIEMER: Under this rule, who can petition --

MS. BROCK: I can? Good deal.

DR. ZIEMER: -- you can.

MS. BROCK: Okay. Well, that's my answer for that one.

The next one -- this is a little peculiar. This would be referring to page 77, 83.9, for the incidence or recurrence. I'm trying to think how to word this to make sure I understand this. If somebody is applying for the SEC status and you're talking about an incident or incidence or occurrence had happened, like maybe you've got an explosion in a used solution plant or maybe somebody -- like my father was burned, or had a dust bag burst over him, he's deceased. The biggest part of these records are gone, and I have filed requests, probably like 12. They're probably ready to kill me. I had to file a fee waiver. I don't even know what I'm doing, so they're going to get all this information. What if that's not there? Hospital records are destroyed after ten years, so this burden is falling upon people -- I do this 'cause I'm kind of nutty, but you've got people that are 80 -- 70, 80 years old, they don't know how to do this stuff. I'm -- I

mean I'm helping them -- as many people as I can do this. I'm going to try to start workshops to help them. But I mean this is -- what -- how much -- how specific do we have to be if there's no information? Do you want to wait to answer that or...

DR. ZIEMER: Let me start this and just in general terms, it would be my understanding of the proposed rule that the incidents that they are talking about are specifically radiation incidents. That is, incidents that lead to exposure that would impact on the calculation of the dose. We -- one of the issues we talked about this morning and the Board will probably address more is the question you are asking, what if the direct -- individuals who directly experienced the incidents are no longer there, what secondary evidence can be used. We'll certainly be trying to address that to the best of our extent. I don't think, other than that, we know the answer to what is certainly a very important question.

MS. BROCK: Okay. I know I had something else with that one, but I just -- I can't remember what it was. I should have written it down.

And then I'm kind of confused -- I don't even know where this was at in the rule, I should have

written it down. If you had multiple job titles, do you have to have 250 days -- say you were a maintenance man, do you have to -- or -- yeah, do you have to be in a specific spot 250 days to petition for this or for this to -- or did I misunderstand that if you had multiple job titles. Maybe you were there seven years, but you were never in one job 250 days. Is that...

DR. ZIEMER: This is being recorded, Ted.

MR. KATZ: Yes, so it would really depend on -- depend on what class -- what the class is that's defined. I mean the class could be defined to cover any number of job categories.

MS. BROCK: So like if you're talking about radon exposure --

DR. ZIEMER: Speak into the microphone, please.

MS. BROCK: Sorry. If you're talking about radon exposure -- like at Mallinckrodt, there were three different types of radon, three types of radium, so I guess I'm very confused. I'm not really sure -- I don't even know how to ask the question, I guess.

MR. KATZ: So if the exposures were -- wherever the exposures occurred, you could define the class to cover whatever that entire area is for which

there were exposures that you believe you cannot estimate the doses for. So it could cover any number of jobs over multiple locations at the site and so on -- at the facility and so on.

DR. ZIEMER: Perhaps Denise's question was --

MR. KATZ: Is that --

DR. ZIEMER: -- what if each job was say 200 days --

MS. BROCK: That's it.

DR. ZIEMER: -- and there were multiple such jobs, but no one of them, by itself, was -- met the 250 criteria, I think is the question that's being asked. Is that correct?

MS. BROCK: Yes.

MR. KATZ: But if -- the question is really whether all those jobs are covered by the class or not. If all those jobs -- it's unreconstructable dose, then they're all bundled together.

DR. ZIEMER: Then they would bundle together is what he's saying.

MS. BROCK: Oh, okay. Okay, makes sense. I see.

DR. ZIEMER: Right.

MS. BROCK: I was -- unless they had maybe three different job titles and only one had radon

exposure and that was 200 days, then they're not covered.

MR. KATZ: If -- I mean the only thing that wouldn't be covered is a job that was -- for which we can reconstruct the doses. That wouldn't be covered. But for any job they were in that had these exposures that we can't reconstruct, it wouldn't matter how many days in each job, they would all be covered, whether they were working -- just because they were working in the general area and those exposures occurred to all these people in all these different job categories, but they were still in the same area and incurring the same exposures.

DR. ZIEMER: But also keep in mind -- again, Ted is talking somewhat generically. Whether or not it applies to your specific case, I don't think he'd want to characterize it that way, so you need to be sure that you understand, he's not necessarily talking about a case. He's trying to be generic.

MS. BROCK: And that's what I was asking, too, in that form. I just was curious because if I have to relay this back to somebody, I kind of want to at least have some sort of guideline as to what I'm explaining to them.

The other thing -- I remembered what I was going to ask about the occurrence. I understand that you need witnesses in reference to the Special Exposure Cohort. Does that -- is that the same for dose reconstruction? Say you have a phone interview and you're sending in supplemental information that has occurrence reports, and if I would have occurrence reports stating that there was an explosion here or 16 workers over-exposed here, but I cannot specifically place a worker there, just know that he was there during that time period, is that burden of proof on me to say hey, he was there?

DR. NETON: I think in the dose reconstruction process we would rely on coworker monitoring data at that point, and we would try to ascertain the names of workers who were present at that incident. And if they were still alive and able to be interviewed, we would pursue that. But we would have to have some sort of evidence that the event actually occurred.

MS. BROCK: And you do take like occurrence reports on that? Okay.

And the only other thing I had, and I don't know if anybody can help me with this. We also have a hematite facility and it's my understanding that

years of coverage at this hematite facility only go until 1968. I guess -- I understand they were no longer under DOE contract. The interesting thing about this is I believe there's residual radioactivity there or contamination. These people have technetium in their water. They can't drink their water. Their water's bottled in and these workers or some of the workers there, even in the nineties, I have huge lists of people that have cancer. What do they need to do to get I guess expanded coverage? Do I go through Department of Energy? Is that even a possibility? Because there's residual contamination there.

DR. NETON: Yeah, I think one thing is we need to discuss a little bit about what coverage means. I'm not familiar with the exact facility that you're talking about, but if the Department of Energy has established that the facility was under contract at a certain period of time, say 1958 through '64, that is the eligibility window for a person to be eligible to file a claim. But the dose reconstruction would actually be performed through that period up until the date of diagnosis. So if a person contracted cancer in 1968, the dose reconstruction would actually consider any dose that

may have been there from continuing operations, if we could determine that, up until that period.

I think the other issue, though, that you brought up is should other workers be eligible to file a claim if their employment started after say our hypothetical 1964 date. And the answer is NIOSH does not set that window, although we do have in progress a residual contamination study that will inform Congress as to the types of contamination that may have continued, but -- beyond the contract dates, but we do not set that date.

MS. BROCK: Okay, 'cause I do know that they -- oh, I'm sorry.

MR. ELLIOTT: But if you -- let me add to Jim's comment, Denise. If you have information -- I think you mentioned a moment ago you might have information about the hematite facility. We don't expect claimants to be burdened with trying to find that, but if you have it in your hands, we'd like to have it so that we can do our study most efficiently and most comprehensively.

MS. BROCK: Oh, absolutely. I don't have a problem --

MR. ELLIOTT: If you'd share with us --

MS. BROCK: Absolutely.

MR. ELLIOTT: -- we'll factor that into our study findings.

MS. BROCK: But the information that I have actually would be residual contamination now. They have I think -- it's my understanding they have 200 unlined, uncapped pits, one that I think contains like a Studebaker. I mean this is -- and apparently there's this runoff and these people cannot drink their water, a lot of these area residents. So my concern is if in fact Mallinckrodt or whatever had -- do you know what I'm saying? -- that that originated there, then perhaps -- and anything I have, I would be happy to share. I mean of anything that would expedite this or help claimants. Thanks.

DR. ZIEMER: Thank you. Again I'll ask the Board -- Dr. Melius has a question.

DR. MELIUS: I'd like to thank both you and your mother for making the long trip here and like -- your mother -- we certainly understand how difficult, even maybe years later, it can be to deal with these issues. And I guess I had two questions for -- I think they're for Larry, but one is really I think for Department of Labor. I think what you're saying is if a claimant dies and the file has to be restarted, a new claim has to be filed -- I

know this is a Department of Labor issue and not you.

MR. ELLIOTT: It is, and I know Jeff and we have another Department of Labor -- Rosa -- Rosa's back there, but I'll get -- they can correct me if I'm wrong. You don't have to start the file from scratch. You just have to submit an EE2 or 3. It's a form that a new survivor would have to put in just to establish their authority as a survivor.

DR. MELIUS: My second question is -- for you, Larry, is this issue on the interviews. And if I recall right from an earlier meeting, you do try to expedite interviews for people that are ill or may become incapacitated -- in a sense you try to move them up in the queue if that is requested? If you don't, I would think it would be something you ought to consider because certainly getting information from a -- you know, a living person who had worked there is certainly probably preferable to --

MR. ELLIOTT: Absolutely.

DR. MELIUS: -- getting it from --

MR. ELLIOTT: It is our intent to capture the story of the individuals, and if their death is imminent and we're made aware of that, we do attempt in all cases to capture their interview as quickly

as possible. And we have done that.

DR. MELIUS: Okay. And can we -- claimants informed of that I guess is the -- are they aware of that issue. As this gets up to whatever it is, 11,000 claims in the queue now or whatever, then I -- I'm not sure we can rely on them calling in and obtaining -- you know, notifying you of the situation. But I think some consideration has to be given to some way of making that known in a way that -- I mean you don't want the process abused, either, but -- 'cause that wouldn't be fair to other claimants, but at least making them aware that if that is an issue, it could be done.

MR. ELLIOTT: Well, as we interact with the claimant population, as they call us, as we -- they talk to us about the status of their claim, as the situation is identified, we react.

DR. MELIUS: Yeah. And I guess what I'm recommending you consider being a little bit more proactive in your notification to the claimants or on your web site, whatever, all -- information is saying should these circumstances occur, let us know and we would try to expedite that -- that process.

DR. ZIEMER: Okay. Thank you for that comment. Yes, Richard.

MR. ESPINOSA: You said there was 150 phone calls. What was the most general concern from these phone calls?

MS. BROCK: I think they were just interested in -- in maybe what was actually found out. I mean the rule. People are very curious about that. Like I said, it's 91 pages. It's hard for me to take all that in and I know that the Special Exposure Cohort, when people look at that, they're assuming that that's one way to avoid timely dose reconstruction. I mean they're -- like I said, they're just very concerned with the time period in itself and the data, maybe a lot of that not being there. And I think that was the biggest part of it, wanting to know, you know -- and basically letting me know they got the letters.

I want to ask one more thing while I was up here. Could anybody give me an answer on the St. Louis thing? I mean is that a possibility that you would consider coming to St. Louis and having a meeting?

DR. ZIEMER: I think the Board is open to considering any such invitation. We are committed in our next meeting to Oak Ridge. We also have to consider another meeting here for the training of

the Board in the use of the computer system, but I think I can speak for the Board that we're certainly open to considering that. It certainly would be -- it's probably a good location. It's pretty centrally located, so in that respect --

MS. BROCK: Okay. Thank you.

DR. ZIEMER: -- yes. I might insert here, maybe ask a question as to whether or not NIOSH has considered some kind of a simplified brochure, once the rule is in place, that would describe in laymen's terms the content of the -- that would -- I think would meet what appears to be Denise's effort to share what this is about with the public, maybe a piece and possibly you've already considered something that could be developed for distribution so that the burden's not on folks such as Denise who may not have all the technical details that are needed to completely capture --

MR. ELLIOTT: Yes, thank you for that. We have anticipated this. We have an effort underway to develop a tri-fold brochure. Can you imagine it being in lay language? I don't know what -- we're going to try to do our best there. It'll be tough. And we've had somebody working on this for the past month and a half, two months almost, making tweaks

to it and as the rule that we wrote changed and things come to light and going back and forth about lay level language and sixth grade reading level, et cetera.

I also want to say that we certainly appreciate people out there like Denise who have just taken on a huge challenge themselves in trying to help communicate and educate the complexities of this whole program. And we certainly don't want to see that effort diminished and we stand ready to help in any way we can. And I would suggest that -- you know, use our web site, Denise. Have folks send in questions or give us a phone call if they've got questions. Once we're through the rulemaking phase on this and we put the rule -- it's a final rule, we'll be able to answer those specific questions about how does this all work, and we'll be at the ready to help you.

MS. BROCK: Thanks.

DR. ZIEMER: Okay. I have next Richard Miller has requested time to speak. Richard?

MR. MILLER: Good afternoon. I was watching the chimes, the wave in the wind over the table. I don't know if others of you noticed it, but it's a bit eerie. Yeah, think about that.

DR. ZIEMER: It started moving a lot when you started talking.

MR. MILLER: The record will reflect that.

DR. MELIUS: The audience stopped.

MR. MILLER: Good point. Good afternoon. Richard Miller with the Government Accountability Project, and just to follow up on the point that Denise had raised about St. Louis, I thought the question that you asked was not could you have an Advisory Board meeting in St. Louis, but could there be some public information session on the rulemaking for the Special Exposure Cohort. Is that correct?

MS. BROCK: That's correct.

MR. MILLER: The record will reflect she's nodding. And so the question -- I guess I'll just reiterate it. I don't know, you know, Larry, or what your staff -- I understand is doing many things at one time, but I have to confess, I pay attention to this stuff as part of my job, and I did try to wrap my mind around this rule, and it still hurts. And I have a lot of questions and I'm still very confused about it, and I think the idea of a public information session somewhere to solicit some kind of public input -- random sampling of normal human beings listening to this, you know, sometimes brings

sort of reasonable people's minds to reasonable questions, and so I would encourage you. I don't have a specific place. I think St. Louis is great if Denise thinks that's the place to do it. If you want to do it in Washington, D.C. 'cause you would get organizational interest to participate, but I would encourage you all to think about a public information meeting with a public comment period that would be afforded. And if it extends the rulemaking period, I think getting it right is more important than rushing it out.

I know that you all worked diligently after the last rulemaking to revise this rule, and I fully appreciate that it wasn't you who was responsible for leaving us with 36 hours to read a rule and comment on it intelligently, and that you did more than your best efforts to get it available sooner and -- several months ago, I might add, let the record reflect. So we are not assigning a responsibility to you or to NIOSH for having taken so much time to get it out. But I think getting it right is more important than getting it out for the sake of getting it out just because somebody says gosh, it's two years and four months since the law's been enacted; how come you don't have a rule?

Well, the good news is you listened to public comments and reworked your rule. The bad news would have been if you took that same mindset and put out an unworkable rule six or eight months ago. So I mean I think you all are to be commended, having read through the rulemaking record, that you did some serious listening to the full array of comments. And not that I fully agree with what you came up with, I think that process of percolation is extremely valuable and I would want to encourage both NIOSH at the leadership level and HHS at the leadership level to think about extending the comment period and having a public forum to take some public input on this. It's too important a part of this statute -- it was the core of the compromise of this legislation between putting everybody in a Special Cohort like RICA was, versus relying on some science-based approach and what happens when that fails. This is the grand compromise of this legislation. So I've made my pitch on page two about extending comment period.

I would like to address, in order of the rule as best I can, several technical points that I did not hear addressed today. And let me start with the really easy one, which was the 250-day provision for

asserting or establishing the endangerment threshold.

The rule says 250 days in a facility. Let me give you an example of a multi-facility where employees went from facility to facility to facility -- Oak Ridge, at Y-12, X-10 and K-25. You had a common project labor agreement at that site going back to the Manhattan Project. You had a common set of workers who moved from completely different facilities, some of which -- they were even managed under different contractors.

The Act, as it has been interpreted by the Labor Department with respect to Special Exposure Cohorts -- this is the DOL rulemaking -- says that you can accrue your 250 days by working in more than one gaseous diffusion plant, even though it says "a facility" in the Act. In other words, when you look in the definition of Special Cohort it says you have to work 250 days in a facility. The Labor Department has chosen to interpret "a facility" to mean any of those three gaseous diffusion plants, in order to accumulate the necessary time.

And I would like to encourage you to think about how you apply that 250 days and whether the "a facility" limitation as it is expressed here is

necessarily delimited by Congressional intent or not, because I don't think the Labor Department has read the law so narrowly and cramped because they wanted to fulfill its intent, and I don't think you should, either, in the 250-day threshold.

Secondly, I'd like to jump to this question of whether or not the -- NIOSH is properly and appropriately limiting the list of diseases. And in -- I think it's in section 83 -- let me just get the section here and the page number so I can refer you to -- the section I'm referring to -- 83 -- is that 13? -- 13, thank you. And on the bottom of page 81, it's little subpart (iii), and in this section which says (reading) if applicable, the identification of a set of one or more types of cancers to which NIOSH's finding that it was not feasible to estimate radiation doses with sufficient accuracy is limited.

And so what's being proposed here I believe is what we heard earlier in the presentation to say there'll be certain organs for which -- will not be included in the Special Exposure Cohort. Now what this phrase, if -- of limiting it to certain organs is a disease cohort. This is not an exposure cohort criteria. And by a disease cohort, what I'm suggesting is that if you only have certain of these

diseases, you will then be in a Special Exposure Cohort.

Congress created 20 -- a list of 22 cancers. They didn't write in there, under the list of specified cancers, 22 cancers unless NIOSH deems otherwise. And it doesn't say in the definition of a Special Exposure Cohort, if you have a covered cancer and it is defined -- rather than -- rather than the criteria for Special Cohort, if it is not feasible to estimate dose to the organs which NIOSH deems it wants to select.

Now I'm not trying to swim against the tide and say that all organs are equally affected, for example, by internal dose. What I'm suggesting is is that -- from the presentation I heard this morning with the two examples that were provided, the radon example and the glove box example -- in both of these cases there was going to be some probability of causation from -- ranging from -- if you were to, for example, look at a biokinetic model and say okay, let's take radon and lung, well, lung is going to have some amount. But you have the daughters and the daughters are particles. The daughters are not exhaled as gases. The particles are alpha particles. You may, through the

mucocilliary* effect, have them come up into your throat. They may wind up lodging in your larynx or in your pharynx or in your salivary gland, or you may swallow them or they may go into your colon and a certain portion of them will excrete.

Now all I'm saying is is that to assume a zero probability of causation for a whole set of cancers, which Congress didn't authorize you to do, invites some degree of controversy. And I think the controversy that's invited here is that Congress didn't say is it feasible to estimate dose to a narrow individual group of organs. They said -- so I'll just leave it at that. I think what's happened is is that you've strayed way far past your mandate, beyond the Exposure Cohort, to create disease cohorts. And I would suggest that we give some really hard thought to whether or not Congress intended to authorize NIOSH to start carving out cancers from the list of 22. Certainly didn't authorize NIOSH to add any, and it didn't authorize them to take them away, either.

The second question that I have has to do with how you know whether or not you can, to use the phrase we've heard today, to cap out the maximum dose. And as Jim Neton said today -- well, you

know, you can always estimate it was a million rem, but you really can't support it. Right? Or whatever some lethal dose is. How do you know you've estimated the maximum dose? In other words, is there a checklist? In other words, this is almost like an epistomological* question. How do you know, given this sort of sparse data that you're working with and you're saying well, we're going to give it the worst case on solubility and then maybe we'll give it the -- we don't really know what all the source terms are, but we'll think what they could be and we'll kind of give them the worst and then -- where -- where do you draw the line on the worst case? In other words, how do you know that, so that if a claimant were to look at your -- say I come in with a petition for Special Cohort and this is a practical problem, and I say geez, you say you can cap out the dose. I say you guys haven't looked at 16 different things, or vice versa, how do you know that when you've capped it you've really looked as far as you can look?

Now we heard today that -- we sort of heard today that if you had capped out the dose, whatever that number is, that would be the number NIOSH would give to DOL to adjudicate for a given claim. Is

that right, Jim?

DR. NETON: No.

MR. MILLER: It's not right.

DR. NETON: No.

MR. MILLER: Okay. Subject to a distribution around it?

DR. NETON: It depends on the case.

MR. MILLER: Well, let's go through the case, because it seems to me it's really important to understand whether we're leaving a hole in the logic here. And the hole in the logic that I'm worried about is that if you're not prepared to adjudicate a claim based on this maximum potential dose, but you're also prepared to say you're not going to put them in the Special Exposure Cohort, then who falls out in the middle here? Maybe you can address that it would be more constructive.

DR. ZIEMER: And could I suggest that -- and you can address this in general -- in a general sense, Jim. I think the point is being raised with the Board to consider, as we go through the rule -- I don't -- I'm a little uncomfortable with --

DR. NETON: You don't want me to get into very -- specifics?

DR. ZIEMER: Right.

DR. NETON: Richard said a lot, and I'm not sure I can remember all the points he raised, but --

DR. ZIEMER: But he's raised some -- you know, a particular case and so on --

DR. NETON: The particular question related to what --

DR. ZIEMER: Generically you can answer, but I think -- more importantly, the issue's being raised for the Board to consider, and that's the point.

DR. NETON: I understand. But the issue of whether or not we would use a distribution or a maximum value really depends upon the data that are available to evaluate the case. If we had some monitoring information at all that would allow us to generate a distribution with some best estimate of the exposure, we would assign a distribution. Lacking that information, though, we would be required to do some upper bound maximum dose that would not likely have a distribution. So it really is a case-specific scenario based on the amount of data available. And I'm reluctant to get into hypotheticals because we could go on and on with that, but that's the short answer.

DR. ZIEMER: No, but I think we hear your point and that's the --

MR. MILLER: Right, I mean you understand the conceptual point, which is, is there a gap in the logic there.

I also would like to -- bear with me a second here -- oh, I'd just like to talk a little bit about the administrative procedures that were discussed a little in the Q and A. It seems to me you have three choices -- maybe there are more available. In terms of what happens if somebody submits a petition and doesn't satisfy all the relevant requirements, and this is the section under 83.11. In other words, they give you -- you give them 30 days, you've got to update the petition, you've got to give them the data that's needed. Then in the preamble to the rule it invites the Board, I believe, to discuss the idea of should there be any kind of administrative review or appeals process for the claimant at that stage. I mean a petitioner -- excuse me, a petitioner. And in the preamble, you know, it doesn't say what the range of choices that the Board could consider, but it seems to me there's three easy ones to think about.

The Board could decide that individuals could bring, on some informal basis, their case to the Board and say geez, you know, I -- you kicked me

out. I think I satisfied all the relevant criteria and requirements and I don't think I've been treated fairly by NIOSH and I'd like you to at least hear it, so you can advise them accordingly if you want to.

Another choice is you could have NIOSH, using the HHS various adjudicatory offices, of which there are a limited number sort of within the branch of CDC that Larry's in, but -- or NIOSH is in, but you know, they do have like an Office of Contract Appeals, so they do have hearing officers, a small hearing officers branch which could hear that kind of appeal. In other words, you just take it to a neutral third party.

DOL, I'm reluctant to suggest anything given they haven't been volunteering any new ideas about how to expand their program lately, but to the degree and extent that they have ALJ's and, you know, Decisions 'R' Us over there, it's kind of their business, you know, that might be another vehicle, though it's taking it outside the ambit of the HHS decision and agencies are usually reluctant to make decisions for agencies that they don't control -- it's an extra -- outside their agency.

But it does -- but I do think there ought to be

some answer as to whether if after 30 days someone responds and you all say look, your petition just doesn't cut it, is that a final agency action, and then their only recourse is judicial review at that point? Do you want to send that kind of stuff to court? Would you rather have some kind of either formal or informal review process in between? And all I'm saying is that the rulemaking opens the question for the Board to think about and I'm suggesting -- it's not clear what the choice points are. It would be helpful maybe if NIOSH could give you some choice points about kind of administratively what's workable or not without speculating.

Likewise -- yeah.

DR. ZIEMER: Could you clarify -- are you talking about inadequate petitions?

MR. MILLER: 83.11, Dr. Ziemer, yes.

DR. ZIEMER: Okay. I just wanted to make sure I understood.

MR. MILLER: Now -- right, because --

DR. ZIEMER: Because there is spelled out the next step if it's turned down.

MR. MILLER: Oh, yes, but that's after you've had an effort to petition to be evaluated. This is

the pre-evaluation process, and what the rulemaking invites in the preamble is should or should you not have some kind of review process after NIOSH makes a determination under 83.11 that's adverse. And I'm -- you know, I know the Board has said look, we don't want to be in the business of reviewing every single one of these, let's streamline this a little bit and that's certainly understandable. The question is what are you going to do with the denials. Do you want to just have them die at that point and then if people are really aggrieved, they go to court? Or do you want to have some sort of intermediate process that they could go to, one way or another? Or take it to the Secretary of HHS, for all that matters. I'm sure they'd love to have more work. That was my opinion. And...

With respect, though, I want to then jump to the second administrative review question which sort of came to mind, which is will the same person in the Secretary's Office who is involved or signing off on the denial, say of a petition for dose reconstruction -- say it comes out of NIOSH, it goes up through the Advisory Board and then the Secretary, for whatever reason, one way or another, whether they accept or reject you advice, say nope,

we ain't going to approve this petition, not even going to guess how it could happen. But it could, and there you are and the claimant says I'm going to write in my appeal and you've got this process that you specify in the rule. To whom does it go? Is the Secretary reviewing their own decision again? Or is it that the Deputy Secretary makes the first decision and then the Secretary's people review the second? Is the same person going to be reviewing their own decision a second time, based on an appeal? And I don't know if that -- administrative decisions have been made or not, but it seems like it would be helpful to spell out some separation between the individual who denies it and the person who may want to review it. Just a thought. I mean I could easily see what the appeal would look like if it went to court. Right? They had a kangaroo court.

I think that's the appeals process. Oh -- and I think that if there's going to be a process to contest these in the Secretary's Office, I don't know if there's a specific procedure that the Secretary has -- I know like at DOE if you get turned down with your physician's panel, you go to the office of hearings and appeals and they've got

their own little sort of administrative process that you follow. Is there going to be some sort of -- sort of clear process that's followed here beyond what's spelled out in the rules administratively within HHS for appeals that would be taken, or for reconsideration of denials? And if there is, could you spell that out in the rule? I guess that would just be helpful to those who need to meander this turf the first few times.

Those are I guess the big -- the big question. I think I heard Mark Griffon bring this up earlier, and it struck me, as well. On page 15 of the -- and it's on the preamble, about the fifth or sixth line from the bottom, it talks about the rationale for whether or not to exclude certain organs in the Special Cohort. And the words that it says here are (reading) only those -- you will only include those in the Special Exposure Cohort if they significantly irradiate certain organs and tissues.

And so now this is sort of a qualitative phrase, and does that mean it is greater than a zero probability of causation? Is it one-tenth of one percent? Is it a 20th of a percent? Is it a 50th of a percent? Once you get into this "significantly" thing, it almost feels like IREP is

creeping in the back door into determining the feasibility of dose estimation, when IREP is a risk-based approach for determining endangerment, not for determining sufficiency of accuracy. And you're having this risk-based approach climb in the back door to look at the question about the sufficiency of accuracy because you're saying which dose is affected.

I think -- again, it's sort of ill-founded, but if you're going to stay with this, and I'm not suggesting that you do -- in fact, I strongly urge you not to, but if you're going to stick with it, please pin down what you mean by "significantly".

Those are the thoughts. Thank you.

DR. ZIEMER: Thank you. That last point was one we discussed earlier in the Board and something we flagged for further discussion, as well, so thank you, Richard, for your comments. They're always helpful to the Board and -- as we go forward.

I think Bob Tabor also indicated -- Bob, please. Thank you.

MR. TABOR: My name's Bob Tabor, Fernald Atomic Trades and Labor Council, work at the Fernald site, have been attending these sessions for some time now. I know most of you probably, you know,

somewhat personally or seen you enough to say -- call you by your first name.

Richard's a tough act to follow there and he certainly can articulate this. At least I can understand what he's saying. I don't know if I can articulate or regurgitate it in the same manner, so to speak, to express what I have on my mind. But this thing instead -- he mentioned -- I wrote down his quote here. He says I wrapped my mind around this rule and it still hurts. Well, I wrapped my mind around this rule, it not only hurts, mine's just about numb. I think I'm getting more confused as time goes on here in trying to learn something about this proposed rule.

It seems to me that the initial Act, as it came out under subtitle B, as I call it, covering silicosis, berylliosis and the 22 cancers, you know, with concern being radiological cancers, that you had certain sites that were covered and called Cohorts. And then we have the balance of the nuclear network out here and possibly workers who have cancers that might be similar to those who are identified in the initial cohorts, and we say well, how do we deal with those? So we have this thing now called SEC, Special Exposure Cohort, and this is

the avenue or mechanism or tool by which to get some type of consideration.

But again it appears to me that we're looking at -- or trying to look at apples and oranges, and I do not really see where the equality as far as criteria in evaluating, you know, individuals' claims. I would think that there would be more balance between the rule -- I mean, you know, the Act relative to the Cohorts and the criteria for the SEC. What I'm hearing here today is, or what I thought I knew, was 22 cancers. What I'm hearing here today makes me believe that we're trying to develop this SEC criteria based around maybe an affected organ dose, and I just really am having a difficult time wrapping my arms around, you know, how this really relates and I'm seeing apples and oranges once again and not a lot of equality as far as the criteria between the two.

I would think, and I guess it's not, but I would think it would be as simple is well, you've got these 22 cancers. Now you're not in the initial Cohorts. You come over here to the SEC, it's going to require dose reconstruction. But I would think you would still be talking about the 22 cancers. I don't know if we are or we aren't. It doesn't sound

like we are anymore. So this is getting very complex in my mind.

And on that note, what I'm wondering is how in the world do you explain this to an applicant? Listen, I'm talking to applicants out there that are having difficulty with their applications, as a union representative, trying to, you know, help them. Not as an authority and not as anybody that says hey, this is what is going to happen, only as somebody to assist them with where you can go to get the correct advice from the people that know if they have difficulty. And I have -- I have worked with a number of people who have made application, and it is a confusing process.

In fact, I just got off the phone yesterday talking to the Cleveland office to try to get some interpretation that came from a letter of final decision out of Washington. And on one hand they say well, it's done. On the other hand they say you've still got another 30 days. Well, do I or don't I? It's done or it isn't. Well, I got my interpretation and they were very helpful and I was thankful for that. But you know, if I can't interpret this stuff, and I've been to every one of these sessions, I can assure you that some of these

applicants certainly don't understand it. And if you have to go back and try to explain this stuff to them, I mean it really gets complex.

Now that's the simple stuff that's complex. What do I do with the stuff that's really complex, like what we're talking about here today? I would just beseech you folks to try to make this as simple as we can, and if it can't be simple, that we figure out some way that we're going to be able to communicate it, because it is beyond me, you know, at this particular point.

That would be mostly my comment. I think Richard probably covered the balance of things that I had some concerns over but would not begin to be able to hardly articulate it as well as he did, but I would concur, you know, with his comments, that they're well worthwhile working through those things and getting some strong consideration. Thank you.

DR. ZIEMER: Thank you, Bob. Do any of the Board members have questions for Bob?

That's okay. And Bob, Larry's staff is going to prepare that brochure that we talked about earlier. It's going to explain all this stuff, that even the Board will understand what it's all about.

Now actually the other point that you raised is

one that, again, was identified earlier. It's that issue of the cancer location and the organ that -- exposed. In simple terms, of course, the analogy is sort of like the smoking analogy. One would not attribute to smoking a cancer other than lung cancer, typically. Well, there may be an exception or two to that. In principle, it goes like that. So we may have to struggle, though, with the ramifications of that. I think Mark raised it early this morning, Jim has raised it, others have. What does that mean, that insignificant exposure to other organs.

But anyway, we thank all the members of the public who have provided the comments to us today. It's been very helpful.

Are we needing a break before we plow ahead? A small break, a little comfort break, it looks like. Let's try to keep it to about ten minutes and then reconvene.

(Whereupon, a recess was taken.)

DR. ZIEMER: We'll reconvene. Oh, let's see, Mark is -- is Mark in the room?

UNIDENTIFIED: Here he comes. He's here.

DR. ZIEMER: Leon, are you there? Leon is not here. We've lost Leon.

(Pause)

Okay, we're back on line. Leon's rejoined us. I'm proposing now we return to the document itself. Let me try something out on you because it's not clear exactly how to proceed -- that is it's not clear to me. It may be very clear to you, but I think we can go back and step through section by section. We've already flagged a number of areas that we need to work on. I think those that require only minor rewording in terms of some clarification, perhaps we can identify what that is today.

Others where there's conceptual issues we need to deal with, we'll just have to start debating them and see where we come out. Is that agreeable? And we'll -- we can go on for a while. Gen Roessler has to leave us at 3:30 in order to get her plane.

DR. ROESSLER: Unless you want me to stay overnight, then we'd have to do some --

DR. ZIEMER: How many are in favor of Gen staying overnight?

DR. ROESSLER: Can we get my family's vote?

DR. ZIEMER: Any opposed?

UNIDENTIFIED: I abstain.

DR. ZIEMER: One abstention. Well --

MR. ELLIOTT: I need some dose reconstructions

done. You want to stay and do a few for us?

DR. ROESSLER: It could be interesting.

DR. ZIEMER: Well, in any event, we'll plow ahead here for a while and just -- I'd like to remind you that we've scheduled a -- I believe a three-hour conference call. It's already on the schedule. Check your schedule now, I believe it's next week on Friday, a week from today. So we have the opportunity for a follow-on session there. It's quite possible we would need an additional session, I don't know, but we may have to look at our calendars now and keep that in mind as a possibility.

There has also been -- we've heard some expressions from some members of the public about the 30-day period. We've had some expressions from Board members. It may be possible to get an extension on that and I've asked Larry to go back and sort of ping the system, as it were, to see how difficult it might be to extend the 30-day comment period, either by another two weeks or four weeks. But in the meantime, we need to move ahead as expeditiously -- regardless of whether it's 30, 45 or 60 days. I think it is important for the petitioners that a rule be in place at the earliest

possible time. But as has also been suggested, we want to be sure to get it right at the same time.

DR. MELIUS: Yeah, along those lines and -- I agree that we need to just move on and assume and -- I think -- but I think we ought to consider the Board making a formal recommendation to Larry, to NIOSH, that they extend the comment period. I think there's been -- we've discussed it before. There's a number of issues that have come up. I think that we're -- the general public as well as the Board's deliberations would benefit from that extension and I think it would be helpful to formalize that -- that recommendation. While at the same time I think we have to obviously move forward and consider as -- act as if we're not going to get an extension. But I think it would be helpful and I wanted to do that while Gen was still here, we make that decision.

DR. ZIEMER: Is that just a comment or are you --

DR. MELIUS: I'd make that a --

DR. ZIEMER: -- now proposing --

DR. MELIUS: -- formal recommenda-- as a motion.

DR. ZIEMER: You're making that as a formal motion. Is that -- does someone wish to second

that?

MR. OWENS: I second that, Dr. Ziemer.

DR. ZIEMER: Okay, Leon. Let the record show that Leon is seconding that. You beat several others to the punch here, actually. That's good.

Now might I suggest as -- to the group as a friendly amendment that we couch that in terms of recognizing, particularly comments from the general public, as well, that indicated a willingness to have a slight extension of the time -- 'cause recognize that in one sense it's the petitioners who are also wanting this to come to closure, so this extends the time.

DR. MELIUS: No, I --

DR. ZIEMER: But we've heard comments from the public, so if your motion could be couched in the form that in recognition of the sentiment that we heard that indicates that it would be helpful in getting the rule right to extend slightly, two to four weeks, so --

DR. MELIUS: That was what I thought I said -- I was trying to say --

DR. ZIEMER: So it's in that framework. Okay.

UNIDENTIFIED: Discussion.

DR. ZIEMER: The motion is open for discussion.

Tony.

DR. ANDRADE: I would just like to ask the question, and it's more procedural than anything else. Maybe Larry -- Larry can answer this or Ted. Would the motion need to be specific at this point in time or could we actually act on the motion and vote at a later date, say maybe during our conference call? I'm just asking in terms of what is necessary procedurally.

DR. ZIEMER: Let me answer your question from a parliamentary point of view. The motion could of course be tabled by -- by motion for vote at a later time. That certainly can be done. The motion, if passed, is simply a motion to convey to NIOSH and thus to the Agency the desire to extend this time. It does not mandate it because they are -- it is in fact the call of the Agency, I believe. This would be simply advice or a recommendation from the Board.

Larry, did you have a comment?

MR. ELLIOTT: Certainly the Board can do what you wish here and -- with regard to this motion. My counsel to you would be to allow me to have an opportunity to explore the Secretary's pleasure on this before you took action on your motion. If you knew -- let's say before you took a vote on this --

that the Secretary would consider it, that might change some people's votes. If you knew the Secretary's pretty adamant that this rule needs to be out on the street in its final form as soon as possible and doesn't see a need to extend the comment period, that he's satisfied with this, then that may change -- change how you might vote anyway. I don't know. But I would think you'd want to have a sense of what -- where the Secretary's at. We will convey to the Secretary's Office that there were some Board members who expressed concern about this and there was some public comment heard about this topic, and we can get back to Dr. Ziemer with what we understand to be the Secretary's position.

DR. MELIUS: And I guess my concern is I would like to make the recommendation for the Board stronger than just that Larry heard from the general public and from some members of the Board, that there's a formal Board vote and -- on this -- making this recommendation that the Agency ask for an extension.

Now the Board doesn't agree -- other members of the Board don't agree with that, then I think we'd like to at least see a vote or some indication, and I don't see where delaying it to see what the

Secretary's pleasure is or disposition is towards this particular thing really would help. I think a request has to be made fairly soon, as well as notification to the public 'cause this is mainly to benefit and improve the public participation in this -- in this particular rulemaking and to improve the public comment.

DR. ZIEMER: Okay.

DR. MELIUS: And waiting till the 29th day isn't going to necessarily help that.

DR. ZIEMER: Are there other comments on the motion, pro or con? An option would be to go ahead and have the vote. An option would be to table until a week from today, by which time one might have the information, and all that would be would be an informal indication up through the system that this sentiment, at some level, exists. It would not have -- would not have the thrust of a formal motion if you did that, so those are the options.

Okay, Tony.

DR. ANDRADE: I'd like to make my position quite clear. I'm not trying to -- I'm not advocating that we move quickly to not communicate the fact that we are -- that we don't wish -- or that we don't wish to consider other comments. But

what I'm saying is that in our deliberations today, as well as the deliberations that are going to take place next week, I think we're going to learn a lot more about the details and specifics about the rule, and that both ourselves as a Board and the public will have had a chance to consider issues with the proposed rule, and that at that point in time we might better be able to send our -- our advice up to the Secretary as to whether or not we should really extend the comment period. I don't wish to cut it off. That's -- at this point in time.

DR. ZIEMER: Roy.

DR. DEHART: I'm not sure that a week's delay will impact, and in view of Larry's comments, there may be some political advantage perhaps with a delay, so I will move to table this motion to a time certain, next Friday week.

DR. ZIEMER: Is there a second?

DR. ANDRADE: I second.

DR. ZIEMER: Okay. This is not a debatable motion. We must vote immediately up or down. If you vote in favor of the motion, then you are voting to delay the actual vote on the main motion until next week. If you vote no, we return to the motion that's before us. Is that clear? We're voting to

table.

All in favor of tabling -- oh, and this requires a two-thirds majority to table. Okay? By Robert's Rules.

All in favor say aye.

(Affirmative responses)

DR. ZIEMER: All opposed, no.

(Negative responses)

DR. ZIEMER: Okay, let me see hands on the ayes. One, two, three, four, five ayes.

And let me see hands on the no's. I --

MR. OWENS: My hand is raised, Dr. Ziemer.

DR. ZIEMER: Leon, I see your hand there. Your virtual hand is raised -- one, two, three, four, five, six -- does not have two-thirds, so the motion is not tabled. The Chair did not vote, but the Chair doesn't have to, it still doesn't have two-thirds.

You probably want to know what the Chair was going to vote. I was going to vote to table, so that just makes it even.

Therefore the motion to table fails and we're back to the main motion, which will be a motion to -- is it to ask NIOSH to consider extending the comment period to --

DR. MELIUS: Either fif-- another 15 or 30 --

DR. ZIEMER: -- 45 or 60 -- yeah, a total of 45 or 60 days -- HHS to extend -- in light of the comments that we've heard today concerning --

DR. MELIUS: Yeah, in order to --

DR. ZIEMER: Yes. Okay. Are you ready to vote on this motion or are there -- okay, I'm sorry. We have two more comments, Henry and -- are you speaking to the motion?

UNIDENTIFIED: Yes, I'm speaking --

DR. ZIEMER: Speaking in support of the motion?

MR. ESPINOSA: Yeah, I'm in support of the motion, but along with the motion I do believe it would help out the Board to have a public comment meeting such as the stakeholder meeting. I believe it probably could be held in -- I believe we're meeting in Oak Ridge in -- what is it, in March?

DR. ZIEMER: The meeting in Oak Ridge is after the 60-day period would be over, so --

MR. ESPINOSA: I still believe that there should be some type of stakeholder meeting for -- to where the Board can review the comments from the public, not just the e-mails and stuff.

DR. ZIEMER: Okay. You're not asking at this time for any change in the motion itself --

MR. ESPINOSA: No, I'm not asking for any change in the motion, just a suggestion.

DR. ZIEMER: Just a comment, okay. Henry?

DR. ANDERSON: I was mostly just going to comment on the -- we haven't had an opportunity too much to hear public comments and I guess I had it, as in the past, we were closer to the end period we may have been able to hear more, I think. We probably, as a Board, could put in the time to get out comments together, but I think it would be helpful potentially to hear more from the public, which is why I was looking at the time. I think we've identified issues. We heard some -- or at least early confusion by a few individuals in the public, so I think it might be helpful to get the word out on that and so we may hear some more from -- they may not have their opportunity to comment if they first see this in the next week or two. So that's my only feeling is I think we could probably get out comments in, but I'm -- I think it is a -- at this time of the year, anyway -- a short time for the public, without a whole lot of roll-out like we had with the last ones with the public comment period. So I think it could be extended. It might benefit us, but I think it mostly would benefit the

public.

DR. ZIEMER: Is there anyone who wishes -- I'll do this evenly -- anyone wish to speak against the motion? Just comments? I think Wanda was next and then...

MS. MUNN: Obviously one could make a case for extending comment periods and extending revision periods for almost any length of time in order to get every knot that we can possibly think of out of the string. But I've heard lots of public comments, and I've read some other public comments, and the most public comment that I hear most frequently, over and over, from every site that I'm aware of, is will you please get on with what you're doing. So when we talk about hearing public comments and being concerned about inadequate time to review the materials that are in front of us, I can't help but be aware that the overwhelming majority of what I hear still is please move forward with what you're doing.

For that reason, I oppose extensions of time that we do not feel absolutely necessary for whatever reason. And in this case, it appears to me that it would -- it's a matter of convenience for us to request more time. We would all like to have

more time, but I hear the public saying please move forward.

DR. ZIEMER: Thank you. So you speak against the motion.

MS. MUNN: I speak against the motion.

DR. ZIEMER: Okay. Now, Mike.

MR. GIBSON: You know, I'd just like to say that there's -- seems like there's been some substantive changes to the draft regulation, and so -- you know, I've heard almost 100 percent from the public today that they want an extension of this because -- because of these potentially significant changes in certain areas that need to be fleshed out and thought about and have ample time to comment on.

DR. ZIEMER: Thank you. Yes, Tony.

DR. ANDRADE: As I mentioned earlier, I'm not against holding back the process, and I agree with Wanda that there is -- there's certainly pressure from even the petitioners and the public to move forward.

On the other hand, I think Mike has a very good point here. There have been substantive changes. Hence I think I would support the motion if it became specific and it gave us time to force us to go home and do our homework, get our comments

together and allow the public to get their comments together, but do so quickly. In other words, provide this issue the attention that it is due. And so I would be in support of the motion if Dr. Melius would say limit the time period to say 15 days.

DR. ZIEMER: Tony, are you asking for -- I think the motion as it stands was a 15 to 30-day extension but it wasn't specific, and you're asking to perhaps amend the motion to be more specific?

DR. ANDRADE: Yes.

DR. ZIEMER: Is that the case, or is this -- I'm not sure it's a friendly amendment or only semi-friendly, but --

DR. MELIUS: Before we try to characterize the amendment, just to clarify, I'm assuming that we go forward with our meeting next Friday and that we go -- 'cause I don't think we're going to hear in a week necessarily that they've changed this. And I think we have to assume that we have to move forward in the meanwhile to start preparing our comments. I think the question may come that as we've prepared comments and start to discuss them, do we want to -- should be period be extended, do we hold off on the -- finalize our comments to when the public's had

more time to participate and understand what's going on, which is to some extent what happened with the public participation sessions the last time. I don't feel strongly about 45 or 60 days. I don't know much procedurally about how that gets played out. I -- always -- usually it's been 30-day increments, but maybe Larry or somebody can explain that to me, if there is any... Usually my sense has been they give a 30-day extension simply because the -- they usually wait till 28 or so days have gone by.

MR. ELLIOTT: Well, it can be a 15-day extension or 30-day or 45. It's whatever time they want to designate. I guess that answers your question.

DR. MELIUS: Yeah.

MR. ELLIOTT: Okay. I'll shut up.

DR. ZIEMER: If it's a 15-day extension, that gives us approximately five weeks after our meeting next week to come to closure. If it's a 30-day, obviously it gives us about seven weeks.

DR. ROESSLER: But now three weeks.

DR. ZIEMER: Okay. Is that right? It's four weeks from today. If you added two, that's six weeks. And if we meet again -- I said -- it may be

late in the day. I was thinking that after next week there would be five more weeks. Isn't that right? One and five still six? Yeah. Well, Gen and I can work out our calculus. In any event, it gives us more breathing room. That's the point. And we may have to have another session before Oak Ridge if we're not able to come to closure a week from today, which is entirely possible, I suppose.

Larry, you have a comment?

MR. ELLIOTT: Our rulemaking experience is that comments are filed to the docket on the last few days of the comment period. And so if that tradition holds in this rulemaking experience, if you're looking for those comments that come forward, you're not likely to see the bulk of them until the last week anyway.

DR. ZIEMER: That's probably true. And in my mind, the main thing we gain is a little breathing space on getting our work done.

DR. MELIUS: But also by -- I mean I felt last time that by -- from both the public participation sessions as well as our deliberations and our conference calls and so forth, our meetings, we -- we got some feedback from the public about our views that helped to inform them --

DR. ZIEMER: You mean the public -- or in the telephone --

DR. MELIUS: We informed the public's view, and I think people decide well, okay, that's being addressed by the Committee. I don't need to address that. They're already aware of this issue and it also I think helped the public understand what was in the regulations and so forth.

DR. ZIEMER: Any comments --

DR. MELIUS: And having said all this, and I didn't mean to have this thing take as long as it has --

DR. ZIEMER: That's all right.

DR. MELIUS: -- and I don't want Gen to have to spend the weekend --

DR. ZIEMER: I'm not sure whether Tony made a formal motion to amend or not.

DR. MELIUS: But I would take it as a friendly amendment and let's -- if that can make this move forward.

DR. ZIEMER: A friendly amendment, so what about the seconder? Leon, as the seconder -- I think you were the seconder.

MR. OWENS: Yes, sir, that's right, Dr. Ziemer.

DR. ZIEMER: Jim has accepted as a friendly

amendment Tony's suggestion that we be specific and make it simply a 15-day extension. Is that --

MR. OWENS: That's acceptable to me, also.

DR. ZIEMER: Okay. So the motion that's before us, as amended in an amicable way, is to request a 15-day extension, or we recommend a 15-day extension. Are you ready to vote?

All in favor of this recommendation, say aye.

(Affirmative responses)

DR. ZIEMER: And opposed?

(No negative responses)

MS. MUNN: I'll abstain.

DR. ZIEMER: Abstaining? Okay. One abstention. Then that motion carries and that does -- that is our recommendation.

BOARD DISCUSSION/WORK SESSION

SPECIAL EXPOSURE COHORT - NPRM

DR. ZIEMER: Now if we could -- how are we doing on time here? Let's go to Subpart A. I just want to step through this by section and make sure there aren't any sort of -- even on sections where we didn't address anything. Are there any changes that anybody has identified in 83.0 that need to be made -- background information. I'm going to go through these pretty fast till we get to the -- yes.

DR. ANDERSON: I just had one question early than that and as we went through it I didn't see it addressed, and that's in the preamble on page 49. Now we talked a little bit about kind of windows and how that fits in, and they have here that NIOSH will discuss with the Board this option to assign doses, and I'm not -- I'm not sure what that means. I don't think there is a mechanism built in in the rule anywhere for that as a...

MR. KATZ: Yes, I actually did address this, but -- yes, this is the question that Jim Melius raised about what do we do about folks with other cancers and with experience outside the window. And that is not an issue for this rule. It's an issue for dose reconstruction, which is why it's not addressed in this rule.

But yes, and I'd offered to talk about thoughts about that issue, but I think we're holding that off until you've finished your work with this.

DR. ZIEMER: It's not a part of this rule, yes. Okay. So I'm back to 83.0 subpart A is the section. That's called background information on the procedures in this part. Any comments?

Then I'm going to move forward. 83.1, what is the purpose of the procedures. Are there any

wording changes or other concerns?

I'll keep moving until somebody stops me. 83.2, how will DOL use the designations established, et cetera.

Then we come to Subpart B, the definitions.

MR. GRIFFON: Just one -- one question on the definitions. I think, Ted, you mentioned that the definition of endangered health was dropped. Can you -- is that worthwhile including, 'cause it's been -- it's been changed.

MR. KATZ: There's no point in including it because it's not -- it's not operative in this rule. There are procedures for dealing with health endangerment, but there's no -- it's not being used as a term that needs to be defined. It's defined by the procedures themselves how you address that. We're not defining health endangerment in any way, as we were before using NIOSH-IREP, so it has no value as a definition.

DR. ZIEMER: Now the terminology shows up several times on page 82 -- satisfying the health endangerment criteria.

MR. KATZ: Right, which is the procedures in the rule addressing.

DR. ZIEMER: Okay. The first place it shows up

is an actual quote from the statute. This is at the top of page 82 where it quotes from the statute, (reading) is there a reasonable likelihood that radiation dose may have endangered the health of members of the class.

The paragraph after that sort of generically uses the same term. It's the middle of the page, (reading) NIOSH will assume for the purpose of this section that any duration of unprotected exposure could cause a specified cancer and hence may have endangered the health.

So again that's just a contextual use of the term, not an official --

MR. KATZ: Let me just explain -- I mean in the old NPRM we gave a technical definition for health endangerment, which is why we had it in the definitional section, because we were using IREP to establish a benchmark. Since that all falls out, there's no -- there's no definition really possible for health endangerment here. It's only used generically, and then there are clear procedures for what you do to address health endangerment in the procedures, which are very simple, but -- so there's nothing to define besides the generic meaning that people would take from it, reading it.

DR. ZIEMER: Mark, are you okay on that?

MR. GRIFFON: I think it's okay. I mean it's defined in this section anyway, so I'm not sure -- and I'm not sure you can put a --

DR. ZIEMER: Well, it's defined generically because it's not an official concept that's used to make a determination, the way it was in the original document.

Anything else in the definition section? Then we are -- come to Subpart C.

DR. ANDERSON: Why isn't there an 83.3 and 4?

DR. ZIEMER: 83.6 is the overview of the procedures. There were some minor wording changes in here to make it more clear. Are there any issues that anyone has with that section in terms of the way it's written now?

There appear not to be. 83.7, who can submit a petition. One of the comments during the public comment periods had to do with that issue, but I believe this clarifies it, does it not? Is there in anyone's mind any issues on this -- apparently not. Okay.

83.8, how is a petition submitted. Roy?

DR. DEHART: This section addresses the form which is yet to be created. I just feel it would be

helpful for us to ask that we see that form as soon as it is created.

DR. ZIEMER: And the form itself does not get codified as a part of the rule, so it could be adjusted readily outside the rule as you gain experience with the form. Is that not correct, Larry or Ted?

MR. KATZ: Well, it can always be adjusted, yes. The procedure you have to go through, though, is once OMB approves the form, you have to get approval for making changes to the form.

DR. ZIEMER: That's just an OMB issue, though --

MR. KATZ: That's right.

DR. ZIEMER: -- it's not --

MR. KATZ: That's right.

DR. ZIEMER: -- a public rulemaking and so --

MR. KATZ: It's entirely --

DR. ZIEMER: That was my point, though.

MR. KATZ: Yes.

DR. ZIEMER: It's really a form that has -- it's a little more flexible than if you put it in here, so you're just -- Roy's just asking to see what it looks like.

DR. DEHART: That's correct, yes.

DR. ZIEMER: No changes here that anyone's -- thank you. Yes, Tony.

DR. ANDRADE: Just a question for my own edification. Will the form, as currently drafted or being drafted, will it essentially contain the questions that are in 83.9?

MR. KATZ: Yes, it's that same information that follows right along with the regulation, but it also provides a lot of explanation to help the petitioner understand what's being asked for.

MS. MUNN: And --

DR. ZIEMER: Wanda.

MS. MUNN: -- approximately what is the time element involved with the OMB approval normally, just roughly? Big guess.

MR. KATZ: Well, that depends. No, it's -- if you were to change the informational burden, then it takes a lot more time because then you actually have to make public notice of the new burden and so on and get an opportunity for the public to comment on the burden and so on, so that could get lengthy. But otherwise, if you're fiddling with the instructions and so on, how much time it takes -- I haven't had to do that. I haven't had to go back to OMB so I can't really tell you, but they have -- I

just have to say, they've dealt with our issues under this program very quickly. Although they have the prerogative to take more time, they haven't. So you know, in -- they've dealt with these things -- in forms, for example -- in matters of weeks and so on.

DR. MELIUS: That's in government time, relatively --

MR. KATZ: Well, we -- yes, we're in government and so we're speaking of government time.

DR. MELIUS: To clarify.

DR. ZIEMER: Any others on that section? Okay. The section 83.9, what information must a petition include. I have a note that on page 75 item Roman numeral (iv) needs some cleanup in the wording. Does anyone have anything prior to that item on 75?

MR. GRIFFON: Just the paragraph right above that, also.

DR. ZIEMER: Paragraph (iii)?

MR. GRIFFON: Yeah, which I had talked about.

DR. ZIEMER: Okay. What was the issue on paragraph (iii)? Well, hold on. Anything before (iii)? Okay, on (iii), Mark?

MR. GRIFFON: I just think it's worth considering possibly editing that sentence, as well,

maybe deleting everything after "as relevant to the petition" where it says "and specifying the basis for finding these documented limitations might prevent the completion" -- so forth, so on. I guess my notion is to -- to not make the hurdle higher for information coming in, you know, for potential viable petitions.

DR. ZIEMER: Let's see, this is a health physicist who's been specifically retained, is it, to address the issue --

MR. GRIFFON: Yeah.

DR. ZIEMER: -- report, or an expert. It doesn't have to be a health physicist.

Actually, isn't that in fact what the person is going to be addressing anyway? I mean that's basically the nature of...

MR. GRIFFON: Yeah, I just -- I don't know, I just -- the way I --

DR. ZIEMER: The documentations --

MR. GRIFFON: -- read that --

DR. ZIEMER: -- of the records --

MR. GRIFFON: Yeah, again --

DR. ZIEMER: -- and --

MR. GRIFFON: I guess the way I -- it depends, I suppose, on how you read that sentence that

"specifying the basis for finding". I mean I'm sure they will provide an argument why these -- this limitations in the data therefore necessitate that this group be considered for an SEC, but -- but they may -- I guess -- I guess it looked to me init-- in the initial read that that was presenting a higher hurdle, that they would have to have more subs-- you know, documents that they may not have access to, to support their -- their petition or their -- their -- their claim here that there's lacking information which may affect the ability to be able to calculate doses for that Cohort.

DR. ZIEMER: So your suggestion is to drop that last part of the sentence.

MR. GRIFFON: That's a -- yes.

DR. ZIEMER: That's a solution. Let's -- others want to weigh in on this particular one, pro or con? Is there a simple way to -- I don't think we're necessarily arguing with the intent of it. You're --

MR. GRIFFON: No.

DR. ZIEMER: -- with the extent to which -- that doesn't mean even to specify the basis.

MR. GRIFFON: I mean if other people don't have trouble with it, you know, I'll just -- maybe I'm

reading it too -- as a hurdle and other people don't see it that way. I'll accept that, as well.

DR. MELIUS: It would seem to me if you're going to put that in there that it would be -- and I'm not necessarily recommending this, so -- it would be a general requirement for the other types of documentation that could be submitted. 'Cause if you look at the top of that page, number (i), that doses were not monitored; number (ii), that they were falsified. But neither of those is there a requirement that the petitioner then specify why that would interfere with dose reconstruction -- those -- or those individuals. All they'd point out is that there were some -- then the evaluation would explore that and -- further.

DR. ZIEMER: Oh, I see now. I would have interpreted "specifying the basis" as in fact doing one of those, sort of saying well, it's -- those are the kinds of bases that you have available. This person would be specifying which of those. That's how I interpreted.

DR. MELIUS: Yeah, that could -- that's how -- I understand, okay.

DR. ZIEMER: That's exactly the same requirement, which of these are you alleging. But

we're all seeing it different ways. Tony.

DR. ANDRADE: So what I would like to propose as a potential simple solution to this is to take the wording down at the bottom of little -- the (iii) paragraph, "for specifying the basis for finding the limitations that might prevent the completion of dose reconstructions" et cetera, and placing that in the sentence preceding these subsections.

DR. ZIEMER: I'm having a little trouble tracking where you are there.

DR. ANDRADE: Okay, I'm on page 75, subsection (iii).

DR. ZIEMER: Right.

DR. ANDRADE: Okay?

DR. ZIEMER: Okay. And doing what now?

DR. ANDRADE: And doing the following, in general. Right where there's a comma and it says "and specifying the basis" --

DR. ZIEMER: Yeah, so that whole phrase what --

DR. ANDRADE: Right, taking that --

DR. ZIEMER: -- was saying that --

DR. ANDRADE: Basically taking that phrase and adding it up to --

UNIDENTIFIED: (2).

DR. ANDRADE: No, to the sentence at the very top of the page.

UNIDENTIFIED: So (2).

MR. ELLIOTT: At the end of (2) -- (2) starts on 74 and ends with your sentence on --

DR. ANDRADE: There you go, uh-huh.

DR. ZIEMER: Must include one of the following elements and specify the basis for finding --

DR. ANDRADE: To -- to specify the basis.

DR. ZIEMER: To specify. Does that solve it?

MR. KATZ: Dr. Ziemer, can I try to help here?

DR. ZIEMER: Yeah.

MR. KATZ: Ted Katz, I'm sorry. But I wouldn't move it up there. The items above are self-sufficient already and that's really confusing. What's intended here -- I mean it's said, but obviously it's open to interpretation or it wouldn't be getting multiple interpretations, but all that's intended here is that if you're going to hire a dose reconstructionist of some sort to evaluate and put together a petition for you, evaluate the suitability of records to be able to complete dose reconstructions under -- as they're completed under this program, then your dose reconstructionist that you're hiring needs to document whatever record

limitations the reconstructionist has found and indicate why these limitations might prevent NIOSH from doing dose reconstructions according to the procedure it uses to do them. So it's -- this is when you're hiring a person to do exactly what -- make the case. That's what it's intended to say, at least.

DR. ZIEMER: Wanda?

MS. MUNN: May I suggest that one of the problems is that the sentence itself appears convoluted. Perhaps a great deal of it could be served by putting a period after "petition" and then saying this report should specify the basis for finding the documented limitations -- a couple of words need to be changed to accommodate that, but leave the phrase essentially as it is, but make a new sentence out of it, starting with "this report should specify".

DR. ZIEMER: That certainly simplifies the reading. It's not clear to me that it necessarily addresses Mark's comments 'cause he thought it was an additional burden. As I said, I thought it was simply explaining what it is he's already doing, but --

MR. GRIFFON: I guess it is. I'm also thinking

of the health physicist who might assist, who is on the outside of the loop here, who will necessar-- most likely not have access to as much information. I'm relieved by the word "might" in the middle of that sentence. You know, "might prevent the completion of dose reconstruction". Yeah, I guess the first read-through for me was that, you know, they have a -- a health physicist might have a collection of documents that they suspect would make it very difficult for this cohort's doses to be reconstructed. But then would they give technical basis that would assure -- you know, but it does say "might prevent" so I'm relieved by that. So -- you know, maybe I'm picking at this too hard. I just -- I just wanted to do it to make sure that we weren't --

DR. ZIEMER: We can revisit this. Let me suggest that we leave it in, but change it the way Wanda has suggested for now. That would simplify the reading --

MR. GRIFFON: Yeah, the reading's easier that way. I --

DR. ZIEMER: We would simply delete the word "and" and maybe say "the report should specify the basis" and then -- and then, Mark --

MR. GRIFFON: Yeah, I think --

DR. ZIEMER: -- I'm going to put the burden on you between now and next week, if you'd study this more --

MR. GRIFFON: Yeah, okay.

DR. ZIEMER: -- and when we get to that -- no, 'cause we need -- we can't do all the wordsmithing as a group --

MR. GRIFFON: Right.

DR. ZIEMER: -- so if you would specifically look at that for next week, and then when we get to that point, if you're still --

MR. GRIFFON: Yeah.

DR. ZIEMER: -- uncomfortable, maybe you would propose an alternative wording on it that would clarify it. Would that be agreeable to everyone? I'm just -- I don't want to -- I want to get to the issues that are a little more --

MR. GRIFFON: I agree.

DR. ZIEMER: -- needy for us or weighty. Mike.

MR. GIBSON: Well, and also it -- you know, it says "health physicist or other individual with expertise in dose reconstruction documenting the limitation of existing records". Certainly -- I'm not a health physicist, but I've been around the DOE

long enough to know the limitations in the records, but I wouldn't be able to specify the basis of the finding. I would just -- so I don't see how --

DR. ZIEMER: Well, the basis of the finding is the limitation if you can identify what that is. So I suspect that's the whole point of the report, isn't it? To identify the limitations that might lead to the --

MR. GIBSON: I guess I was just trying to say providing the documentation that demonstrates that the records are inadequate, rather than writing a report, is all that I was trying to suggest.

DR. ZIEMER: Well, I guess however -- whatever form that takes, that's the report. Whatever that person submits for that purpose, so -- okay, comment noted.

The next paragraph, we also had a little problem on the wording, that we thought it should be cleaned up. I have a suggested cleanup on it, but maybe Roy has one, also.

DR. DEHART: The way I would word it, very quickly, a scientific report published by a governmental agency or published in a peer-reviewed scientific journal that identifies dosimetry and related information that is otherwise unavailable --

parenthetical phrase -- for estimating the radiation dose of employees covered by the petition, period, full stop.

DR. ZIEMER: Okay. I had almost exactly the same wording, with the exception of adding the word "technical", a scientific or technical report that -- some people distinguish between those -- by a governmental agency or published in peer-reviewed scientific journal, et cetera.

Mark.

MR. GRIFFON: And did you -- did you -- I missed the end of that sentence. Did you drop off the "and also finds"?

DR. DEHART: Yes.

DR. ZIEMER: Because that report may, as we discussed before, may not necessarily be dealing with this issue head-on. It may be for some other purpose and may not have such a finding in it, per se, but could be used for that.

DR. DEHART: In fact in reviewing the records yesterday, we found such a report that dealt with cancers. Cancer was unrelated to the individual, but the doses that were in there were related (inaudible) no value to the individual.

DR. ZIEMER: Okay. Is that recommended change

agreeable? Can we take it by consent for just a clarification of the wording. Okay.

Let me ask the reporters if they got the wording. They probably did, they're very good.

Okay. The other item that I had flagged here was the very end of the this section. It would be at the top of -- yes, 76, where we said that those items identified as Roman (i) and (ii) might actually become part of 83.11. That would be the whole item (3), and -- Ted has suggested that in that case it would be the whole item (3).

Ted, have you had a chance to look at this further? Is it your judgment that in fact it should be moved? I mean does it make more sense to be under 83.11 in terms of the --

MR. KATZ: Yeah, I can't speak for -- that's -- actually I'm not supposed to say what --

DR. ZIEMER: All right.

MR. KATZ: -- what should be, but I can see how it could go in there and work in there, yes.

DR. ZIEMER: Looking at the titles of the topics, is it under the right topic? It's what information must a petition include, versus what happens to petitions that do not satisfy.

MR. KATZ: Right.

DR. MELIUS: I think, having looked this over, I think the problem is it sort of falls in between, because it -- as I would see the process, a petition could be initially accepted and NIOSH goes to get further information on it and is unable to confirm that the exposure incident took place. Then it goes back to the -- NIOSH goes back to the petitioner seeking this additional information.

DR. ZIEMER: Well, let me ask this. Is it confusing to leave it here or is it okay here?

DR. MELIUS: I think it's potentially confusing, simply because it's -- people are going to look at it and think it is part of the original petition. It's not part of the original --

DR. ZIEMER: But on the other hand, is it --

DR. MELIUS: -- but it --

DR. ZIEMER: -- confusing if it's under 83.11, if it falls in between?

DR. MELIUS: Depends on how -- I think in both places it depends on how it's written, and I think -- I think our recommendation should be that it should be clarified. I think NIOSH, as it redrafts the final regulation, should just clarify and determine what the best position is for it. I don't think we --

DR. ZIEMER: Okay, so we might be comfortable with just pointing this out --

DR. MELIUS: Yeah.

DR. ZIEMER: -- and asking that that be clarified.

DR. MELIUS: Right.

DR. ZIEMER: Obviously we're not asking that it be changed, but it needs to --

DR. MELIUS: Well --

DR. ZIEMER: -- integrate better.

DR. MELIUS: -- we -- I'm also asking that point (ii) there, confirmation from two employees who witnessed, be changed. I don't think that is a fair --

DR. ZIEMER: Oh, we flagged that, that's --

DR. MELIUS: -- requirement. That's a -- that's a separate issue, no matter where it -- this ends up, yes.

DR. ZIEMER: Where it is. Okay. But we can agree to simply -- our recommendation on the whole section will be to clarify --

DR. MELIUS: Yeah.

DR. ZIEMER: -- in terms of where that fits in. Now let's talk about the (ii) versus the -- confirmation by affidavit from two employees who

witnessed the incident. Couldn't the -- couldn't the petitioner be one of the two?

MR. KATZ: Well, I --

DR. ZIEMER: This does not preclude that, does it?

DR. MELIUS: Well, we were told it does, that the interpretation was -- has that changed?

DR. ZIEMER: If the petitioner witnessed it --

MR. KATZ: I really can't speak authoritatively as to how it would be interpreted, but certainly you can raise whatever concern you have as to what that should mean.

DR. MELIUS: I think we should recommend that it be -- it include the petitioner.

DR. ZIEMER: It may include --

DR. MELIUS: May include the petitioner. But I also am concerned about the situation which an incident occurred a number of years ago. There could be situations where the people exposed no longer are surviving, but there certainly could be credible evidence from their spouses about -- who may not -- or other workers who may not have witnessed the incident but heard about the incident, whatever. I think the credibility of that information has to be evaluated in some way, but I

-- given how far back we're going with some of these, particularly AWE facilities and how -- I think how poor the documentation is, that we have to leave open the possibility that records may not be found yet there could be credible information that such an incident did -- did take place.

DR. ZIEMER: I would understand the thrust of this to be, at the outset, that if you had the two witnesses, whether it's the person plus one other, you sort of -- you're already in. But the case where you had one or even none is not really addressed.

DR. MELIUS: The problem, though, is that they've approached this and I think it's awkward. I'm not sure there's a -- what the best way is. What they're doing is saying first NIOSH is going to go and look for the documentation. When it can't find the documentation, it's going to go back and look for this medical evidence, which is -- actually comes from the first announcement of proposed rulemaking. And then secondly this confirmation by affidavit, which I think is new. I don't remember that being in the first one. It may have been, but I missed it if it was. So this is comes second. I agree with you that it could also be supplied up

front, either sets of information, so it is confusing. And no matter what we decide on this or recommend on this, that -- somehow this process needs to be clarified. Maybe it's a separate section. Maybe it can be part of the petition or with an alternative to provide it later or whatever. But if you look at the top of the page, "if NIOSH is unable to obtain records or confirmation of the occurrence of the incidence from sources independent of the petitioner" -- a fellow worker and -- I understand what they're trying to get at, but it's --

DR. ZIEMER: No, it's the case where this incident doesn't show up anywhere until all of a sudden this particular case mentions an incident that --

DR. MELIUS: Yeah.

DR. ZIEMER: -- is not identified anywhere else.

DR. MELIUS: Right.

DR. ZIEMER: Then you go back and say okay, is there someone else that's witnessed this.

DR. MELIUS: Yeah, and then I --

DR. ZIEMER: Or is there medical evidence.

DR. MELIUS: Right.

DR. ZIEMER: And either of those, NIOSH is now saying we will consider those as evidence to go forward. They don't say it will qualify, but it may. So it takes them the next step. But beyond that, a single witness or no witnesses and this third -- this thing we talked about earlier, the hearsay evidence, I don't know what we do with that but we may want to address that, also.

Roy has a comment.

DR. DEHART: I understand totally the reason for the two employees that we're talking about now. My only question would be is there a standard of legal evidence that requires this to be two in addition to the actual case filer. So I think somebody should look into that. If it's not an issue, certainly two...

DR. ANDERSON: It doesn't have to be an individual petitioner. The petitioner could be a union, in which case if they had an individual that reported to them the case or the incident, then that person reporting and another, so it doesn't -- it would seem --

DR. ZIEMER: That's the two people, yeah, right.

DR. ANDERSON: (Off microphone) (Inaudible)

Yeah, if you're the person that's actually, on your behalf, filing, you shouldn't be penalized because somebody else who has a third party filing on their behalf would get to count them, so I think the two is somebody plus the initial reporter is probably useful.

DR. MELIUS: Yeah, then I think if we had a number (iii) if -- under there, if -- you know, employees, you know, present at the time of the incident are not -- or have died or otherwise not able to locate them, that other -- you know, other types of, you know, verbal reports, you know, could be submitted and would be evaluated.

DR. ZIEMER: Okay. Let me see if there's any consensus on the (ii) being two, any two, including if the petitioner's a -- as a recommendation. We can ask for clarification, but --

DR. MELIUS: Yeah.

DR. ZIEMER: -- is there anyone that thinks it ought to be two beyond the petitioner -- assuming the petitioner's a single person. Apparently not.

DR. DEHART: (Inaudible) suggesting changing the wording them from two employees to two -- well, we're saying it could be -- the petitioner could be the surviving wife. Is that what you were

intending?

DR. ZIEMER: Two witnesses, one of whom could be the petitioner if the petitioner actually witnessed it.

UNIDENTIFIED: Not just hearsay, yeah.

DR. ZIEMER: And then there's a separate suggestion that perhaps a section (iii) be added dealing with the issue of lack of a second witness or lack of any witnesses.

UNIDENTIFIED: (Inaudible)

DR. ZIEMER: And I don't think we can wordsmith that here, but -- and I don't even know from a legal point of view what makes sense. My intuition is that we ought to try to grapple with it, but --

DR. MELIUS: I'll give it a try and then the lawyers can go at it.

DR. ZIEMER: You want to try to come up with some wording?

DR. MELIUS: They're just lawyers.

DR. ZIEMER: Well, give us a -- this is a straw man -- this is a straw man, what do we do in the case where there isn't --

DR. ANDERSON: (Off microphone) I mean if there isn't, the likelihood of it actually getting ultimately approved, there's probably --

DR. ZIEMER: Probably low, but there ought to be a mechanism for dealing with these cases where there's survivors who've heard of -- of something. Okay. So you'll take a crack at that.

I'm going to pause a moment and see how we're doing on time. It's 4:00 o'clock. We're scheduled to go till 5:00 and we can continue to plow ahead. Are there other travel concerns? Anyone going to be needing to leave to go catch a plane?

DR. MELIUS: A number of us have to leave at 5:00 so -- we have a 7:00 o'clock flight, so...

DR. ZIEMER: Okay, no later than 5:00.

MR. ESPINOSA: (Off microphone) (Inaudible) schedule for the next meeting?

DR. ZIEMER: We have scheduled a telephone conference a week from today. Does everyone have that on their calendar, 1:00 to 4:00 p.m. Eastern Standard Time. We have scheduled a meeting in May in Oak Ridge, May 19th and 20th. It's -- it probably would be prudent to schedule -- in fact we should schedule it today if we're going to -- even if we --

MR. ELLIOTT: Another teleconference.

DR. ZIEMER: Another teleconference.

MR. ELLIOTT: I'd like to get it in the *Federal*

Register.

DR. ZIEMER: And it would be prudent if we scheduled that no later than first week of April.

DR. MELIUS: A conference call.

DR. ZIEMER: And I'm basically out of the loop all -- till the 3rd, so -- no, I'm out of the loop through the 3rd.

How does the 4th look to folks? Any -- Leon, are you still on the line? Did we lose Leon?

MR. GRIFFON: Can I ask, while he's dialing, Larry, the Oak Ridge meeting, is that -- have you got a location for that?

MR. ELLIOTT: It is in Oak Ridge.

MR. GRIFFON: It is in Oak Ridge, not Knoxville?

MR. ELLIOTT: It is in Oak Ridge at the Garden Plaza -- is where your lodging would be, but the -- I believe the meeting room is going to be over at the mall.

DR. ZIEMER: Yeah, Leon?

MR. OWENS: Yes, sir.

DR. ZIEMER: I don't know why we keep losing you here, but --

MR. OWENS: Dr. Ziemer, I've checked my phone to make sure and I don't know what's going on,

but --

DR. ZIEMER: Well, it may be at this end. In any event, we're talking about a follow-on telephone conference call, possibly for April 4th.

MR. OWENS: April the 4th?

DR. ZIEMER: Yeah. Were there any conflicts here in April?

UNIDENTIFIED: What time?

DR. DEHART: I would be happy to call in if NIOSH will provide me with a satellite phone. I'll be in China.

DR. ZIEMER: Make us feel bad. Make us feel bad.

DR. MELIUS: Let's see, if we did in the afternoon, what time would that be in China? We may want to offer you the --

DR. DEHART: I'll call in.

MS. MUNN: It'll be early morning the next day.

DR. ZIEMER: Those that are going to be in this country, what -- is the 4th okay? Shall we do a 1:00 to 3:00 again, is that -- or 1:00 to 4:00?

Okay. We're back to the document itself, 83.9 on page 77. It's a brief new section. Any comments on it? Or actually it's 10, I'm sorry.

DR. MELIUS: There's a misprint there.

DR. ZIEMER: No, it's -- no, it says it satisfies all relevant requirements under 83.9. I just read the wrong number. It's 83.10 -- 83.10, top of 77.

Okay, how about 83.11? Okay, I had flagged -- and actually this is now covered by Jim's item (iii). I had flagged on page 78 that we would need to consider the issue of what to do if -- about witnesses if there are -- or the survivors if witnesses are deceased from a, quote, incident. So I guess that part's covered. Anything else on 83.11?

DR. MELIUS: I think there's the issue in the preamble. I believe this is the place. It is the review of petitions that don't satisfy and do we want to recommend an administrative process for that.

DR. ZIEMER: Okay, this is paragraph (b), is it not, after 30 days -- (reading) the date of notification NIOSH will notify the petitioner of its decision to evaluate the petition, or its final decision that the petition has failed -- is that the part that...

Now --

DR. ANDERSON: We have said we don't want to

review those.

DR. ZIEMER: Right.

DR. ANDERSON: Should there be an administrative process.

DR. MELIUS: Wasn't it originally that they -- everything came to here.

DR. ZIEMER: This is basically responsive to our previous recommendation, that NIOSH will handle these -- and basically they are petitions which in some way or another are inadequate and get sent back, that they're not -- unevaluated petitions.

DR. MELIUS: I think what -- and Larry, correct me -- I think NIOSH is asking the public to comment on should there be a process -- administrative process, and I think Richard laid out some of the options -- Richard Miller -- some of the options for that, one of which is the Board, and the other would be administrative remedies within or outside the bar-- are there others that -- I guess I'm asking Larry, Ted or somebody...

MR. KATZ: I mean we don't have other ideas, if that's what you mean, other than it's either going to be in HHS, an administrative group in HHS is going to review it or -- I mean you made a decision about the Board before, but you can of course revoke

that decision. I mean --

DR. MELIUS: Well, the decision about the Board was that we wouldn't review all of them. If we have a review process or -- they're going to come up anyway.

MR. KATZ: I mean this actually was abiding by the Board's directions very directly. It was we're going to get all the positive ones anyway that pass muster. It was what should happen with the ones we --

DR. MELIUS: Well, we expect you to provide an answer, not another question.

MR. KATZ: Well --

DR. MELIUS: I mean now you're kicking it back to us.

DR. ZIEMER: What's being asked here really is what does the petitioner -- what options does the petitioner now have. Is there a way to appeal -- obviously they can provide more information and have it reconsidered, because part (c) actually allows for that. (Reading) Based on new information, NIOSH, at its discretion, may reconsider a decision not to select.

That's one option that's built in here, it appears, that the petitioner has additional

information. Are you asking what if there's no additional information but they just don't think the decision was the right one, that the petition in fact is adequate and should have been considered.

DR. MELIUS: They feel that it -- the petitioner feels that it's adequate and maybe not in a position to obtain more information or whatever to satisfy what NIOSH said is wrong with it or why it doesn't qualify, and I think the question is should there be an appeal mechanism.

DR. ZIEMER: Maybe we can frame it this way. I don't know that the Board has to come up with the answer to that. We may raise that as a question to be considered going forward, ask the staff to consider what appeal mechanism there would be for a petition that was -- what I'm saying is we don't have to come up with the change for the rule. We can direct the staff --

DR. MELIUS: No, well, I think we have to make a -- we have to decide whether we want to make a recommendation that there should be a process. And my personal feeling is that there ought -- there should be a review process on that, an appeal process, that should be within the Department.

DR. ZIEMER: Do others want to weigh in on that

and if we reach a consensus then we can include that. Okay. Tony?

DR. ANDRADE: Perhaps I'm just being dense this afternoon at this hour, but again, I refer people to 83.16. Recall the fact that we talked about, quote, evaluated petitions, whether positive or not, and that --

DR. ZIEMER: But these are unevaluated. These are unevaluated.

DR. ANDRADE: Once they are evaluated. Okay. Once they are evaluated.

DR. ZIEMER: No, we're talking about the ones that do not get evaluated. They simply get turned down because --

DR. MELIUS: It's incomplete.

DR. ZIEMER: -- they're incomplete. The petition never really gets evaluated. NIOSH says there's not enough information here -- or you don't meet the requirements for having a petition. Yes, that is a form of evaluation.

DR. MELIUS: It gets evaluated as to whether it meets the requirements. It doesn't get evaluated as to whether it -- the class qualifies as a Special Exposure Cohort.

DR. ZIEMER: Yeah, and maybe we need a

different term 'cause this talks about evaluating the petition and that other section talks about evaluating the petition. One is an evaluation --

MS. MUNN: This is an application.

DR. MELIUS: Wait another half-hour, we'll confuse you even more.

DR. ZIEMER: That in itself is perhaps a semantics issue that needs to be clarified. The ones in section 83.16 do have an appeal process. They have been evaluated as a petition. These are ones where they have decided not to evaluate them. There's a petition and it is not going to be evaluated 'cause it's inadequate or incomplete, which in itself is an evaluation, so...

So the question right now is does the Board feel that there should be some mechanism for petitioners whose petitions fail to meet the requirements for evaluation to be reviewed -- for that decision to be reviewed. Jim has suggested there should be.

Wanda, you're...

MS. MUNN: At some juncture there has to be a no. And if we're not going to accept this no as no, then of course what's the next step is the question here. And my question is, and is that next

step then the no? Where does no become no?

DR. ZIEMER: Just like with your kids, is it the first no that really counts?

MS. MUNN: Uh-huh, or is it the second no or the third no?

DR. ZIEMER: When is no really no? I don't know.

DR. MELIUS: I think actually Bob's ahead of me, so --

DR. ZIEMER: Bob, go ahead.

MR. PRESLEY: When this petition is turned down at this time, do they get any type of a notification that says why they're being turned down?

UNIDENTIFIED: (Inaudible)

MR. PRESLEY: Okay, then if -- then it's explained.

DR. ZIEMER: Rich and then --

DR. MELIUS: If I re--

MR. ESPINOSA: Go ahead, go ahead.

DR. MELIUS: I'm sorry. As I recall from our previous discussions of this, the Board wanted to remove itself so that we wouldn't be into -- it was in some sense an issue of time involved, also, that we wouldn't be repeatedly reviewing, saying go back for more information and then come back -- and so

this would -- process would stretch out, that the process would be facilitated by having NIOSH directly dealing with the issue of obtaining -- determining whether or not these petitions contained adequate information to qualify. And I think that -- I think that makes sense. We shouldn't be -- the Board doesn't need -- have to be involved in continually reviewing all these petitions.

At the same time I feel that the general public should have some measure of appeal from a -- you know, an arbitrary decision or a bad decision made by a governmental agency and that providing some process within the government for people doing that is appropriate and fair -- doesn't necessarily involve us in the...

DR. ZIEMER: Rich?

MR. ESPINOSA: With the recommendation that Dr. Melius made, I'm in favor of -- the main reason why is on page 25, second paragraph, operations of concerns, as a building and construction trade member, you know, a lot of times I don't understand what's being done in the facility or facilities, for that matter. And you know, to be real specific of the operations in the -- of the -- of the stuff going on in the facility, I don't know if it can be

done from a person from the building and construction trades or janitors or the guards, for that matter.

And the same goes with -- you know, on page 27 it almost kind of seems -- you know, you've got to be real specific for the petition not to get thrown out, and I'm not sure how specific some -- some of these claimants are going to be.

DR. ZIEMER: Henry?

DR. ANDERSON: I mean it seems to me there's kind of two decisions. One, do you want a formal mechanism or do you want to have -- based on new information. New information could be NIOSH looks at it and says boy, this is a tough call. I come to the Board and say what do you guys think, and we say well, why don't you go ahead. I mean that's new information, we have given some information, but it isn't the formal appeal process where you have to file documentation or something like that. I mean that -- I would -- seem to me there's enough in here that if somebody really felt it was an egregious problem, that could in and of itself be new information. So it's a matter of if you -- do you want to have a formal process, which would be -- it goes into a process that the petition might then

feel they have to hire legal assistance to go through that process or not. I don't know what other sorts of decisions are appealed, but that could have financial ramifications on the individual that might -- if we say formally you're going to have this process, then that is the process they have to follow.

DR. ZIEMER: Let me insert something here, make sure we're all in the same place. I believe that this is already the second no. The first no is in item (a) where -- what happens to petitions that do not satisfy the requirements. NIOSH notifies the petitioner of any requirements that are not met and assists them in getting new information and gives them another 30 days to revise it. Then a new -- then the clock starts again. And this thing called the final decision is no a second time. So I believe what we would be talking about now is, is there yet another loop, 'cause this has two loops in it already. So an additional appeal, if you want to call it that, I think is yet a third no.

Now is -- are we all on the same page on that? Do I understand this correctly, and that was your understanding when you raised the issue that --

DR. MELIUS: And I think the issue is that

there are -- they've received two no's from NIOSH and then should they have the right to have that second no reviewed by another party.

DR. ZIEMER: Somebody, and it may be the Board.

DR. MELIUS: Originally the party was going to be the Board. The Board said -- it was a little bit more complicated, a different way, but the Board said we didn't want to be the reviewer and have to deal with all these and there's some other procedural issues, so should there be a -- you know, an out -- a third no, a review of that second no by another group. And if there's an administrative process within the Department for doing that, that's another possibility and I think some of our struggle with this is that we're not real sure what the process is within the Department.

At the same time I think we don't want to be -- have to -- if that review becomes an automatic or that -- then it's going to end up being that much more that we have to do. Is that practical, and maybe that may -- it's an option.

DR. ZIEMER: I think we also have the issue of the defined role of this Board. We do have a very specific role in recommending Special Exposure Cohorts. We don't -- I think we don't have a role

in sort of -- if I can call it adjudicating Departmental decisions. It's quite true that this decision does have something to do as to whether a Special Cohort is recommended, so we're not completely out of the loop, perhaps. But I've expressed this concern before that we not get involved in the staff work of NIOSH, that we are focused on our sort of legislated responsibility, so -- you know, whatever -- if there's a review process, I would hope it would be something within the Agency. But it looks like there -- one review has already occurred and, you know.

DR. MELIUS: Well, but so -- but the two no's are from -- the first two no's come from -- come from Larry, I guess. And I guess if somebody seeks a third --

DR. ZIEMER: So the third time, go ask your mother.

DR. MELIUS: Well, who's Larry's mother, and if they can tell us who his mother is, you know, that's -- that process would be -- and I agree with you. At the same time it's sort of a gray area since I guess our role is -- of the Board is to review the point of views, but the evaluation of those petitions and the final recommendations and -- once

they're accepted. And I'm unclear how much we should be involved in accepting them.

DR. ZIEMER: Okay. The issue is, should there be this additional appeal; and if so, who. And I'm going to suggest we leave it there right now. Unless -- unless somebody's -- really knows how -- what the answers to those are, 'cause we can revisit it next Friday. And maybe we'll all have bright ideas.

Okay, that's 83.11. 83.12 -- oh, I'm sorry, Rich. Did you have something else and then -- I'm sorry.

MR. ESPINOSA: Can we step back to 69 real quick and --

DR. ZIEMER: Sixty-nine?

MR. ESPINOSA: Paragraph (c), class of employees. Can we change facility to facilities?

DR. ZIEMER: Where are you again?

MR. ESPINOSA: Page 69, class of employees, a group of employees who worked or work at the same DOE or AWE facility, can we change that to facilities?

DR. ZIEMER: Let me ask if this language is from the legislation or where does this definition of class of employees come from? Because that in

part might tell us whether we can --

MR. KATZ: Can you hold one second for that? I need to find a piece of paper.

DR. ZIEMER: Okay.

(Pause)

MR. KATZ: Okay, thank you. This is -- I mean this is the issue that Richard raised about multiple facilities. That's what -- that's what's being proposed here, that we say multiple facilities instead of, you know, facility. And Richard pointed to then language that has to do with specified cancers -- let me find you the language -- bullet down here -- yes, the difference between DOL using multiple facilities to aggregate 250 days and our using -- requiring it be at a facility under this rule is that it's different sections of this legislation with slightly different language that makes the requirement at a facility, and our language has no wiggle room, is sort of the bottom line. Our language leaves, you know, no room for interpretation that it could be multiple facilities, whereas the DOL language has some wiggle room and they were able to interpret it as multiple facilities, or I believe that's how that occurred, you know, though I haven't --

DR. ZIEMER: So you're saying this definition comes from the legislation which defines it this way?

MR. KATZ: So that -- so the legislation specifically talks about that these are classes at a facility and at that facility, singular. Which we explain and you'll see that discussion in the preamble, and that's why we were constrained to limit it to a single facility, but it's -- we had different statutory language to deal with than DOL.

DR. ZIEMER: Thank you. So at the moment then I guess that suggests that -- that it may have to stay that way because of the definition in the law. Okay. Thank you.

83.13, page 79. Okay? Moving ahead? 83.13, top of 80, I've got a flag here. Item (1) near the top of the page.

DR. MELIUS: I'm not sure that we're capable of discussing this at this point in time on a Friday afternoon, but --

DR. ZIEMER: No, but -- but we can --

DR. MELIUS: -- it's a big issue.

DR. ZIEMER: We can frame the issue so that people can give it some thought between now and next Friday.

DR. MELIUS: And that's what I was about to... Right, yeah.

DR. ZIEMER: Jim, I think you raised it, so you want to reframe it for us?

DR. MELIUS: And I think the framework for that issue is the same framework from our previous comments, that NIOSH has not really defined in any detail how this operates, how they will make this determination. They've changed it somewhat from the last time, but there's still a very vague framework for making this determination that a dose can or cannot be reconstructed with sufficient accuracy. And I think the framework for the question is have the changes that they've made and has the currently language adequately defined that, and I certainly -- I don't believe it still does.

They -- I should point out that it -- I think -- believe it points out in the preamble that -- some later steps that NIOSH will do to try to clarify some of this issue and -- including providing some examples. But we've -- we were also told that last time and we still don't have the examples to go over, so -- and that -- so if we're going to do it on a case by case basis with sort of a case law that would develop from these examples, I think that

leaves us -- to me it's still problematic.

DR. ZIEMER: Could you clarify for me the nature of the issue? Is it -- it's more than a wording issue. It is an issue of whether or not in fact what is described here can be done. Is that correct?

DR. MELIUS: Whether it provides adequate --

DR. ZIEMER: Or if they're --

DR. MELIUS: -- guidelines --

DR. ZIEMER: -- telling us how -- how it will.

DR. MELIUS: Yeah, that it could lead to arbitrary conflicting decisions because as this is applied that I don't believe that there would be -- arbitrary and inconsistent decisions, because as this is applied it doesn't provide enough of a framework or guidance for determining whether or not a dose can be determined with sufficient accuracy.

DR. ZIEMER: In which case the comment might be along the lines of what you had just said.

DR. MELIUS: Correct.

DR. ZIEMER: Without saying what -- how you would change it to address it, but raising the issue.

DR. MELIUS: Correct.

DR. ZIEMER: Tony?

DR. ANDRADE: I really believe that this is an issue of a definition of sufficiency. I think NIOSH has done a very nice job in the following sub-bullets in pointing out examples of the types of information that might provide sufficient accuracy. However, it's -- if you think about it, there can be an infinity of particular situations. And I think that this is going to have to be handled on a case by case basis. And if we belabor this or if we try to put down exact definitions of what constitutes sufficiency, we're going to end up with a 1,000-page document. So I think that we've got to keep in the back of our minds that most of these petitions are really going to be unique situations.

DR. ZIEMER: Who else has comments on this one? Okay, we'll -- we'll plan to revisit it Friday.

The bottom of the page I have a note -- I think, Wanda, this was yours -- that --

MS. MUNN: Yes, it was.

DR. ZIEMER: -- the wording here gives the idea that dosimetry data are not important or something along that line. That's not what we want to convey, but -- we want to convey that --

MS. MUNN: Right. I had suggested language that I can throw out next Friday.

DR. ZIEMER: Okay. So Wanda will reword -- or give us some suggested language Friday. Thank you.

Top of 81 I've flagged. It's the issue of not feasible to estimate radiation doses. Jim, I think that was also possibly your issue?

DR. MELIUS: Well, the -- that was actually I think the first issue, but I think what the issue there is in section (iv) and in section (iii) at the bottom of the page is the tissue-specific cancer site issue, that what they're proposing is that this will somehow be limited to particular cancer sites and I think it's stated more directly at the bottom of the page under number (iii), (reading) NIOSH's finding that it was not feasible to estimate radiation dose with sufficient accuracy -- (inaudible) one or more types of cancer, that whole section there. (Reading) identification of a set of one or more types of cancers to which NIOSH's findings that it was not feasible to estimate radiation doses with sufficient accuracy.

DR. ZIEMER: And the issue is centered around the debate on whether or not, if you could -- if you can't estimate the dose for a particular organ, say the lung, can you do it for any other organs.

DR. MELIUS: Yeah, or --

DR. ZIEMER: In essence is what it does, other than saying it's got to be very low and therefore insignificant.

DR. MELIUS: Yeah. Yeah, what is the test going to be to evaluate why -- when you can't -- you've already determined you can't do it for one organ system, how can you say you can do it for another? It really -- actually let me restate -- I don't think I stated that correctly, is that when you made a determination you cannot determine the dose with sufficient accuracy, how can you then limit that to just an organ system or a series of organ systems.

DR. ZIEMER: And Jim may be able to comment on that. Actually I can probably think of some ways that could be done, and others might --

DR. MELIUS: I think two.

DR. ZIEMER: But let's hear from Jim.

DR. NETON: I just want to say one thing. I think that we have to insert the key word "plausible" in there, a "plausible" dose, which is not -- well, it's not an implausible dose, by definition. You know, it has to be a plausible dose that you could come up with to reconstruct that makes sense.

The converse of that, though, is if there were implausible doses that don't pass the reasonableness test that one could assign and do a dose reconstruction for other organs, one could do that. I mean it's --

DR. MELIUS: But I have trouble --

DR. NETON: And do a dose reconstruction.

DR. MELIUS: Without belaboring this, but have trouble when distinguishing how you separate -- if it's not feasible to do with sufficient accuracy, then what is a plausible dose --

DR. NETON: Let's take the case of a uranium inhalation where it's plausible to -- it's implausible to come up with an upper limit -- it's plausi-- you could come up with an upper limit based on -- you have no monitoring data at all. You know the person worked with uranium and you know that uranium concentrates in the lung, so lung cancer. You could do a -- you couldn't do a dose reconstruction for the lung. However, you could come up with implausible exposure scenarios where one would have to inhale five pounds of -- if one inhaled five pounds of uranium, which would be biologically -- choking the person, and one could still calculate a dose and demonstrate that the dose

reconstruction was done and the probability of causation was very small for certain remaining organs, then you've done that. I mean you have to be able to pass the reasonableness test here.

One cannot assume people inhaled five pounds of uranium and say that those cancers should be considered part of the Special Exposure Cohort -- or those doses, those organs.

DR. MELIUS: Can I just add, though, I think you're -- that's what you're intending to do, then I think you need to state that much more clearly in these regulations. I mean I can agree with the concept. I have trouble seeing how you operationalize it and how you make that determination from going from -- in different situations and if my recollection's right, these two paragraphs on page 81 is the only place where you describe how you will do that. You don't define these terms and this just -- so I think an alternative is not that we reject this, but also is --

DR. ZIEMER: Or maybe spell it out, and actually I --

DR. MELIUS: Spell it out.

DR. ZIEMER: You actually -- you end up going

in reverse. You say okay, if I had a cancer in this organ, what kind of loading in this other part of the body do I need to deliver sufficient dose to this other -- to this organ. And if it's, for example, takes five pounds of uranium in the lungs to give you some --

DR. NETON: This is a real example --

MR. GRIFFON: These are all --

DR. NETON: -- this could happen.

MR. GRIFFON: The thing that we -- and I've talked to Jim during the break on this and yesterday a little bit, too, but I mean -- I mean the question then I have is you didn't have adequate information about the radiation source term to make a maximum estimate, and yet now you're telling me in this example that it was only natural uranium that was -- you know, so we're loading with uranium, almost five pounds --

DR. NETON: Well, I was --

DR. ZIEMER: Oh, no --

MR. GRIFFON: -- when in fact if --

DR. NETON: Well, the source term would have to be known, but I mean at least in terms of its type.

MR. GRIFFON: And then if the source term's known, in many examples you're going to be able to

estimate a maximum pretty well.

DR. NETON: No, no --

MR. GRIFFON: I mean I --

DR. NETON: That's not correct. If we don't know what type of operation was done -- grinding, welding, cutting and there's fumes all over the place -- we have no idea of knowing what reasonable or -- what's the word we're talking about -- plausible doses could have been received by this person. But we do know that the person could not physically inhale five pounds of uranium -- I don't care how much uranium was there, but we would have to know, you're correct, that uranium was present and there were no other radionuclides in the mix.

Remember, we're not saying that we're going to do this for every case. This just allows us the option to set, in those circumstances where we can clearly define it, the option to do that so that we don't end up granting SEC status for cancers that are implausible under these exposure circumstances. So they have to pass the reasonableness test, in my mind. You cannot --

MR. GRIFFON: Yeah, but --

DR. NETON: You cannot grant SEC status for a person who would have to inhale an unreasonable

amount of material to develop that cancer.

MR. GRIFFON: I don't disagree with that, but you -- you see the logic, also, that if you have insufficient information, you don't have dosimetry, you don't -- you know, you're limited on dosimetry data, you're limited on source term data, you can't even calculate a maximum --

DR. NETON: We're not saying we would do that --

MR. GRIFFON: -- and then you're turning around and saying you have a pretty -- pretty tight handle on --

DR. ZIEMER: You're not saying you don't have any data. Right?

MR. GRIFFON: -- (inaudible) involved.

DR. NETON: No. If we knew it was a uranium facility and there was --

DR. ZIEMER: But you don't know anything about --

DR. NETON: -- a transuranic contamination --

DR. ZIEMER: -- the magnitude of the amount.

DR. NETON: Right.

MR. GRIFFON: Or -- but I mean that -- that's the question I have is that, in the absence of all that other data, how -- you know --

DR. ZIEMER: Well, I guess --

MR. GRIFFON: -- how -- how sure are we that -- that these are the only isotopes involved? I'll give you a --

DR. NETON: That's a different issue.

MR. GRIFFON: I mean not to --

DR. ZIEMER: That's a different scenario, though, than you're talking about.

DR. NETON: That's a different issue.

DR. ZIEMER: Then in fact you in fact open the door to all the others anyway, don't you?

DR. NETON: I suppose. That's what the Board would weigh in on once we provide -- move the petition forward.

DR. ZIEMER: But what you're asking for is guidance on how they would do what they're describing here right now.

DR. MELIUS: Yeah, it looks like --

DR. ZIEMER: You're --

DR. MELIUS: Personally, unless I see more detail how this would be operational as to how these determinations would be made, I find it very hard to accept this approach, but -- you know, I think we're open and...

MR. ELLIOTT: For Mark's scenario it wouldn't

be a cancer-specific class definition.

DR. ZIEMER: If you had all --

MR. ELLIOTT: We would go with an SEC, the whole -- I mean the whole presumptive list.

DR. NETON: Yeah.

MR. ELLIOTT: Because we don't know what the radionuclide in the mix is.

MR. GRIFFON: Right, right, right, but I'm turning it -- I'm turning it around and saying give me an example where you would know the mix but you couldn't calculate a maximum. I think Jim attempted to do that -- I still have to think through some of these what-ifs myself, but --

DR. NETON: This would be used on a limited basis when we knew there were certain scenarios that did not pass some reasonableness test. I think radon is another one of those we talked about, or any situation -- it's not just internal exposure. It's any situation where you have partial body irradiation. The entire body is not uniformly irradiated, which happens most of the time in internal exposures, especially with these actinide elements that only deposit in two or three organ sites to any appreciable degree. We're not saying the dose is zero, but we're saying that we feel that

there are going to be certain circumstances --

MR. GRIFFON: And they had --

DR. NETON: Okay.

MR. GRIFFON: And they had no other exposures or the other exposures can't be reconstructed.

DR. NETON: We would have to be very sure that there were no other exposures that we could identify --

MR. GRIFFON: I mean I'm just -- I'm just wondering how often that scenario is even plausible and whether --

DR. NETON: But do we need --

MR. GRIFFON: -- it's worth going down this path.

DR. ZIEMER: May not.

DR. NETON: All we're saying is we're allowing for that possibility. We're not saying we're going to exercise it in every case or required to exercise that in every case, but we need to -- think that we should have the option available to do that.

DR. ZIEMER: Okay. The issue's been framed and we know what kind of question to ask on that. I think --

MR. GRIFFON: (Inaudible) --

DR. ZIEMER: Yeah.

MR. GRIFFON: -- one more thing on that. I think that -- and this is part of the reason I would be -- more time is helpful for me, also. In the preamble -- I know the Health Physics Society commented on this, those comments must be on the -- on the web site?

MR. ELLIOTT: Oh, yeah.

MR. GRIFFON: Okay. So it might be -- that might be useful for us to look at before the conference call.

MR. ELLIOTT: Yes, the --

MR. GRIFFON: So we get a sense of what their rationale was for --

MR. ELLIOTT: The previous NPRM and the docket that contains all the comments are on the web site.

DR. ZIEMER: Yeah. And incidentally, that would be useful if you would all look at that before the next conference call to acquaint yourself with those comments.

Now on page -- oh, I'm sorry. Henry.

DR. ANDERSON: I just read it as not permissive, but as will. And if you look at top of 81, it says if it's not feasible to estimate the dose with sufficient accuracy, will also determine whether such finding is limited at tissue-spe-- so

it says in each case you will determine that as opposed to you may. I don't know if that -- so in every -- every instance, you will consider that, that it might be limited.

UNIDENTIFIED: (Inaudible)

DR. ZIEMER: On page 82 I had flagged the endangerment to health, but I think we've discussed that already. It's used generically here. Were there any other issues on that?

Okay. Anything on 83? On 84 we -- on 83.14 we had the issue of evaluating a petition by a claimant whose dose reconstruction could not be complete under 42 CFR 82. I guess we've already discussed the issues pertaining to that, so this section in itself -- I don't think there was anything there, unless somebody can identify it for me. I'm sort of just marking which ones look like they're okay as they stand here.

83.15, Ted pointed out some things there that were new, but are there any items there of concern?

Okay. 83.16? 83.17?

DR. ANDRADE: On 83.16, just a minor point.

DR. ZIEMER: Uh-huh.

DR. ANDRADE: On item (c), it says HHS will issue a final decision on the designation and

definition of the class. It just doesn't say how long it'll take the Secretary to do so.

DR. ZIEMER: So you're suggesting there should be a time limit in there?

DR. ANDRADE: Right.

DR. ZIEMER: Let me ask the staff if they can sort of react to that. Would that be helpful and wouldn't there ordinarily be a time value in there?

Let's see, you have 30 days -- going back to (b), provide the petitioner 30 days to contest a decision. And then, Tony, you're asking after the 30 days --

DR. ANDRADE: After the 30 days.

DR. ZIEMER: -- is this a year later, a month later, that day or --

DR. ANDRADE: Right.

DR. ZIEMER: -- or is there a need for --

DR. ANDRADE: Given the importance of this whole SEC rule to the public, I think that -- it might not please the Secretary, but it would be prudent to put in there a deadline.

DR. ZIEMER: Without us specifying it, could -- what the number of days is, could we suggest that that be considered and an appropriate...

UNIDENTIFIED: I think so.

DR. ANDERSON: (Off microphone) If the petitioner has 30 days to file an appeal, the Secretary ought to have 30 days to respond.

DR. ZIEMER: Well, I'm suggesting that our comment not specify what the time should be, but -- right. Okay.

DR. MELIUS: Thirty-one.

DR. ZIEMER: Fair's fair, right.

DR. MELIUS: Thirty-one.

DR. ZIEMER: 83.17, I guess we all begrudgingly agreed that we can't change the role of Congress.

DR. ANDERSON: (Off microphone) But we can limit them to five days.

DR. ZIEMER: They limited themselves to five days. That is, the staff did.

83.18? Okay, I think we've pretty well framed out the issues that we need to discuss next time. I commend you all on -- we're going to get done here I think by 5:00.

Let me ask if there are any final comments on the document before we leave it today. I know there's a fatigue factor that sets in. You're all in favor of --

UNIDENTIFIED: There's a document?

MULTIPLE SPEAKERS: (Inaudible)

DR. ZIEMER: No, I think it's been very helpful. There are just a few items we need to spend some time on. It might very well be that we can be pretty close to closure at the next meeting.

Wanda has a comment.

MS. MUNN: Do we anticipate addressing the prologue during our discussion?

DR. ZIEMER: Well, keep in mind, the prologue or whatever the proper term is -- preamble, is not really part of the rule. However, if there are errors or changes that should be made in that, I suppose we should try to identify those. There's no reason we shouldn't. Right? So certainly that's game for comment, to say you know, this statement in the preamble is wrong or should be revised in some way. But it's not part of the rule.

MS. MUNN: I understand.

DR. ZIEMER: It's just an explanation of how they proceeded and dealt with the comments.

Okay. Let me ask if there are any housekeeping items -- I think Cori's gone. You can turn in your prep hours for this meeting to Larry. Turn in your travel vouchers to Cori as soon as possible. Any other items to come before us?

Leon, are you still there? We've lost Leon

again. Well, Leon will figure out that the meeting has ended.

We have some information on our next meeting at Oak Ridge.

MR. PRESLEY: (Off microphone) One other thing, do we want to come up with a date when we want to come up here and do some training -- another meeting in Cincinnati?

UNIDENTIFIED: The whole Board.

MR. PRESLEY: The whole Board?

DR. ZIEMER: This would be a date after the Oak Ridge meeting, I presume. And therefore -- the Oak Ridge meeting is May 19. We would be talking perhaps about -- this is strictly training? It wouldn't be a -- would this be a -- this doesn't have to be an announced session of the Board and open to the public to come? That presents some problems in terms of viewing records and so on.

MR. ELLIOTT: You've got some Privacy Act issues.

DR. ZIEMER: I guess we can identify a date and -- but not have Cori execute anything until we find out how that can be done.

MR. ELLIOTT: I think it is important for the -- all Board members to experience what those

yesterday in the working group experienced. My suggestion to you would be, to get around this -- the Privacy Act constraints that we all are going to operate under here -- that you identify a -- maybe two working groups to do the same thing that the working group did yesterday. Just get familiarized with the information that you're going to see. That way you won't have a quorum of the Board. It doesn't have to be a public forum. You can look --

DR. ZIEMER: We won't be conducting business.

MR. ELLIOTT: Won't be conducting business. It is a working group session to familiarize, as an individual, yourself with the administrative record. That would be how I would suggest you go about it. That way we can accommodate that with real finished cases and full administrative record to support the decision.

DR. ANDERSON: How long a training period? Or could we do this as --

DR. ZIEMER: One day.

DR. ANDERSON: A whole day or --

UNIDENTIFIED: Five or six hours.

MR. ESPINOSA: Or two half-days.

DR. ANDERSON: No, I was just wondering, if we broke up into two groups, we could -- if one came in

one day and the other the next day --

MR. ELLIOTT: That's fine.

DR. ANDERSON: -- we wouldn't have to --

DR. MELIUS: 'Cause we didn't meet --

DR. ANDERSON: -- disrupt your group too much --

MR. ELLIOTT: No, no.

DR. ANDERSON: -- by scheduling groups in on different days.

DR. ZIEMER: But they wouldn't necessarily have to be back to back, either, if we had --

MR. ELLIOTT: No.

DR. ZIEMER: -- people that had schedule conflicts.

MR. ELLIOTT: No, we had essentially -- let's see, five -- six of you go through yesterday. Right?

UNIDENTIFIED: Five.

MR. ELLIOTT: Five? Well, Dr. Ziemer was there --

DR. ZIEMER: But I didn't go through the first part with them. I only was there for the --

MR. ELLIOTT: Okay, so we --

DR. ZIEMER: -- discussion on the procedures.

MR. ELLIOTT: -- got five done -- We got five

done. You have seven more individuals who should go through this experience. If you break that out into two groups, you could come any time you wish.

DR. ZIEMER: Right.

MR. ELLIOTT: As a group. I'd just ask that. I don't want to get seven individual dates where we --

DR. MELIUS: Can you circulate some possible dates and see if we can all fit into them for -- for these visits?

MR. ELLIOTT: I will ask Cori to tap you for your availability, right.

DR. ZIEMER: But let me ask, on working groups don't I have to actually appoint them and charge them with a task?

MR. ELLIOTT: Yes, you do.

DR. ZIEMER: And so it might be helpful simply to get three of you and four of you and have a working group chairman for each, and that chairman can work with the other two or three and with Jim and find a common date and we don't have to sit here in the full group. Who is it that needs -- it would be Tony, Jim, Wanda -- and I would be involved 'cause I haven't gone through a full session. And Leon and Henry. Okay. So Tony, are you willing to

be the group leader --

DR. ANDRADE: Yes.

DR. ZIEMER: -- for one of the groups? It would be you, Jim, Wanda and -- is that one group?

UNIDENTIFIED: Leon.

DR. ZIEMER: Okay, and let's say -- and Leon.

DR. ANDRADE: Okay.

DR. ZIEMER: And then you simply find a -- work with Jim and find a date.

DR. ANDRADE: Okay.

DR. ZIEMER: Okay. And then Henry -- and you be the chair of the other group? Okay, and then it's you and Mike and Roy --

DR. DEHART: No.

DR. ZIEMER: No, you were there already. You're -- he's going to be in China -- and me.

DR. ANDERSON: Okay.

DR. ZIEMER: The three of us. Right?

DR. DEHART: Paul, I would suggest this be later than sooner. It needs to be closer to the time you're actually going to be starting again.

DR. ANDERSON: So after Knoxville -- or after --

DR. ZIEMER: Yeah, this could be in -- this could be June, July time.

DR. MELIUS: Yeah, that's what I was going --

DR. ZIEMER: So there's no big urgency.

DR. ANDERSON: We can talk about it at the next meeting.

DR. ZIEMER: Okay, so those are the two working groups and they are simply charged with the responsibility of learning the system. Okay?

Is there any other business to come before us today?

MR. ESPINOSA: For the -- for the meeting after Oak Ridge, after the May -- I found it a lot easier on me if -- you know, we're kind of scheduling two meetings in advance and it's been a lot easier for me to move my stuff around. Is it possible that we can schedule the next meeting now?

DR. ZIEMER: Sure. Or we can at least identify and have -- Cori would have to confirm it.

DR. MELIUS: There were some issues I thought that came up regarding the task order business and timing and so forth. I thought Larry had to clarify those.

MR. ELLIOTT: I would ask that you hold off on scheduling your following meeting until we get into May. Let's -- if we can do that at May, it would make a lot more sense to me --

DR. ZIEMER: But it's probably not going to be till July.

UNIDENTIFIED: (Inaudible) time frame.

DR. ZIEMER: Yeah.

DR. MELIUS: Well, if you could even start circulating something beginning of May when you -- when you feel you're comfortable in terms of timing.

MR. ELLIOTT: Yeah. Yeah, we could do that. Maybe at -- in advance of the May meeting. First of May we could tap everybody's availability. We'll have it at the May meeting.

MR. ESPINOSA: It's just, you know, if we could schedule a lot more in advance.

DR. ZIEMER: Right. Anything else for the good of the order? Then this meeting is adjourned.

(Meeting adjourned)

1

C E R T I F I C A T E

STATE OF GEORGIA)
)
COUNTY OF FULTON)

I, STEVEN RAY GREEN, being a Certified Merit Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript was reduced to typewriting by me personally or under my direct supervision, and is a true, complete, and correct transcript of the aforesaid proceedings reported by me.

I further certify that I am not related to, employed by, counsel to, or attorney for any parties, attorneys, or counsel involved herein; nor am I financially interested in this matter.

WITNESS MY HAND AND OFFICIAL SEAL this _____ day of April, 2003.

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STEVEN RAY GREEN, CVR-CM
GA CCR No. A-2102